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Cecilia Lee
Preventive Medicine and Biometrics
Uniformed Services University
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Abstract

Title of Dissertation: The Effect of a Decision Aid on the Quality of Colon Cancer Screening Decisions

Cecilia Lee, Doctor of Public Health Candidate, 2012

Dissertation directed by: Galen Barbour, MD, FACP, FACHE
Director, Health Services Administration
Preventive Medicine and Biometrics

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the United States. CRC might be prevented with screening, but there are several screening options, each with risks and benefits. Current recommendations encourage providers to share decision-making with patients to weigh risks, benefits and uncertainties. The use of decision aids has been widely advocated as an effective means for patients and providers to reach agreement when there are two or more valid treatment choices, such as in the case of CRC screening. This study was designed to determine the quality of CRC screening decisions when a formal decision aid was available.

In order to examine the quality of colon cancer screening decisions, both with and without the use of a decision aid, 280 study participants were randomly assigned to receive usual care (n = 140) or a video about colon cancer and screening options (n = 140). Participants in the intervention group received information on risks and benefits of all available screening options. Usual care participants received standard care without the decision aid. All participants were then surveyed using the Decisional Quality Instrument (DQI) to determine (a) their knowledge about colon cancer screening and (b) their preferences for a modality by which they would be willing to

be screened. A total of 76% of the surveys were returned.

The study observed significantly higher knowledge scores in the intervention group (80 ± 18) compared with the control group (72 ± 15). The difference in mean knowledge scores between the two study groups was larger among those without a college degree. Value concordance was not significantly higher in the intervention group. The majority of participants chose colonoscopy. Preference for colonoscopy was positively associated with physician recommendations and prior experience with colonoscopy and was lower among women. The decision aid is a promising tool in improving knowledge about CRC, especially among patients without a college education. However, more work is needed in further refinement and validation of the DQI instrument and the decision aid.

THE EFFECT OF A DECISION AID
ON THE QUALITY OF
COLORECTAL CANCER SCREENING DECISIONS

by

Cecilia H. Lee

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Dedication

I dedicate this work to Cody, Maddie and my husband, Dong Lee.

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A. Significance and Specific Aims

The purpose of this study is to determine the impact of a decision aid on colon cancer screening decisions. Colorectal cancer (CRC) is one of the leading causes of cancer morbidity and mortality in the United States, even though the vast majority of new cases of CRC could be prevented with proper screening [1, 2]. There are currently multiple screening options, all of which carry benefits as well as risks [3]. Further, experts disagree on the best method of screening [3]. Colon cancer screening decisions are considered "preference-sensitive decisions" because there is a lack of clear evidence supporting one screening method over the others [4]. For such situations, incorporating patient preferences along with clinical guidelines is recommended to facilitate shared decision-making. Decision aids are increasingly used in the process of shared decision-making to advise patients about risks, benefits and tradeoffs. Earlier studies have shown that decision aids generally increase knowledge, clarify values and improve realistic expectations about medical interventions, but information reflecting the role of decision aids in improving the quality of colon cancer screening decisions is lacking [5-12]. A previous study in 2007 measuring the quality of breast cancer decisions concluded that measuring decisional quality is both feasible and important [13].

The George Washington Medical Faculty Associates (MFA) offers a wide range of colorectal cancer screening services but provides no educational intervention beyond consultation with a physician. The majority of MFA patients who are screened for colon cancer undergo colonoscopy. To determine the impact of a decision aid, this

randomized controlled trial examined whether the use of a decision aid improved participants' knowledge and increased value concordance, the extent to which patients' choice of screening test reflect their values and preferences. This project used the decision aid developed by the Foundation for Informed Medical Decision Making, a non-profit organization whose mission is to develop and evaluate decision aids to facilitate shared medical decision-making. Decision aids are tools – usually in the form of a video, pamphlet, worksheet or web site – that are designed to complement physician counseling by (1) providing information about the disease and treatment options, (2) clarifying values and (3) providing decisional guidance to ensure a patient's treatment choice is consistent with his or her values [14]. The Foundation's decision aid is part of the Cochrane Inventory, the world's largest library of quality decision aids. There are several libraries of decision aids but the Cochrane Inventory of Patient Decision Aids is the most well-evaluated. This project also administered a decision quality instrument previously developed by Karen Sepucha, PhD, a leader in decisional quality studies.

The primary goal of this study was to determine whether the decision aid increased patient knowledge about colon cancer screening. The secondary goal of the study was to assess the degree to which use of the decision aid affected participants' choices and how well their choices matched their values and preferences.

Specific Aim 1: To determine whether use of the decision aid increased participants' knowledge of colon cancer and different screening options.

Hypothesis 1: Exposure to the educational intervention is positively associated

with increased knowledge scores.

Specific Aim 2: To determine whether use of the decision aid increased value concordance, i.e., whether participants' chosen treatments meet their stated values and preferences.

Hypothesis 2: Exposure to the educational intervention is associated with increased likelihood of patients choosing a test that matches their values and preferences.

B. Background

B.1 Facts About Colon Cancer and Screening Options

Colorectal cancer (CRC) is the second leading cause of cancer-related death in the United States [1]. In 2009, there were a total of 146,970 incident cases and 49,920 deaths from this disease [1]. Ninety percent of these cases could have been prevented in theory if screening procedures had been performed in a timely manner [2]. The purpose of CRC screening is to allow early detection of adenomatous polyps, which are pre-cancerous tissue growths on the mucosal surface of the colon that can progress to colon cancer if left untreated. The vast majority of polyps associated with colon cancer are believed to originate as benign adenomatous polyps, which take 7 to 15 years to develop into life-threatening cancer [15-17]. It is now widely accepted that the identification and removal of these adenomatous polyps, through regular colon cancer screening, can assist in prevention of colon cancer. Compliance with effective screening procedures can be anticipated to significantly reduce the incidence and mortality rates of colorectal cancer in the United States.

Many screening options are available but their accuracy and the level of evidence supporting their use varies considerably. Each test also comes with advantages and disadvantages with regard to optimal test frequency, cost, accuracy, convenience and acceptability. Table 1 shows a side-by-side comparison of colon cancer screening choices based on the decision aid provided by the Foundation for Informed Medical Decision Making.

B.1.a Fecal occult blood test (FOBT). FOBT is a non-invasive, at-home

procedure conducted annually to detect blood in the stool, which is collected by placing a small sample of stool on a chemically treated card. Different collection and lab techniques (e.g., rehydrated vs. unhydrated FOBT and one-card vs. three-card FOBT) can be used with FOBT, and these, in turn, affect the test characteristics and effectiveness. A false positive test can result from dietary peroxidases, iron intake, and non-cancerous gastrointestinal bleeding. FOBT is the simplest, most affordable and extensively studied screening test for CRC. No current studies address any adverse effects of FOBT. The sensitivity of FOBT depends on whether rehydrated test cards are used. One-time unhydrated FOBT has sensitivity between 30%-40% for cancer but hydrated FOBT can have sensitivity as high as 50%-60% [18]. The effectiveness of FOBT in detecting CRC and reducing mortality has been demonstrated in three major randomized trials [19-21]. In the Minnesota Colon Cancer Control Study, annual FOBT (three cards) reduced CRC mortality by 33% after 13 years of follow-up [21].

An alternative method for measuring blood in the stool is a fecal DNA test, which works by detecting abnormal DNA of tumor origin, indicating tumor-associated mutations in the adenomatous polyposis coli (APC) gene, the p53 tumor-suppressor gene and the K-ras oncogene [20]. Fecal DNA is an emerging technology and there is not yet sufficient evidence regarding its effectiveness in reducing mortality. However, one study demonstrated that fecal DNA has higher sensitivity compared with traditional FOBT [20]. More studies are needed to provide better estimates about its performance characteristics.

B.1.b Flexible sigmoidoscopy (FSIG). FSIG is an invasive, moderately

expensive endoscopic procedure that directly inspects the lining of the left colon (from rectum to descending colon or rectum to splenic flexure). The patient must clean out the bowel the night before using a laxative and/or an enema may be administered right before the procedure. Any physician, physician assistant or nurse practitioner trained to use the sigmoidoscope can perform the procedure without sedating the patient. FSIG lasts about 15-30 minutes, depending on whether polyps are removed during the procedure. However, the examination does not detect pre-malignant lesions and cancer of the right colon. Cramping and bloating may occur during the procedure. Bleeding and perforation, although rare, are possible complications. Colonic perforation occurs in 0.88 per 1,000 examinations [19]. It is estimated that one-time screening with sigmoidoscopy detects 68%-78% of advanced neoplasm [22, 23]. There is no direct evidence from randomized controlled trials to support the use of FSIG. However, case-control studies have demonstrated that patients who die of CRC are less likely to have undergone sigmoidoscopy compared with their matched controls without colon cancer [24, 25].

Combination screening with FSIG and FOBT is one of the recommended strategies and may be more effective than either used alone. If used together, the FOBT can be done every three years and FSIG every five years. A nonrandomized clinical trial conducted by Winawer and his colleagues concluded that combining the two tests appears to increase the likelihood of early detection of CRC while reducing the mortality rate by 43% [26].

B.1.c Colonoscopy (CSPY). Typically, in CSPY, a highly trained

gastroenterologist (sometimes a colorectal surgeon) uses a long, flexible, lighted tube to directly examine the whole length of the colon. Bowel preparation is required for CSPY and is commonly accomplished by using a strong laxative the night before the exam. The procedure lasts approximately 30 to 60 minutes and moderate sedation is given to minimize discomfort during the examination. After the procedure, patients are not able to drive and need some recovery time at home until the sedative wears off. The recommended interval for CSPY is 10 years after a normal examination and shorter intervals if abnormalities are identified. It is the most invasive and expensive test available for CRC screening. CSPY, the only screening test that provides direct examination of the colon, is considered by many experts to be the gold standard for CRC screening. The sensitivity of CSPY for large adenomas is greater than 90 percent [27]. While CSPY is considered a reference standard, no screening trial has determined that CSPY can actually prevent colorectal cancer. Indirect evidence supporting its effectiveness comes from Muller and Sonnenberg's case-control study, which reported decreased CRC incidence by 40-60% [28]. The best evidence about the benefits of CSPY comes from the National Polyp Study [29]. A team of researchers at Memorial Sloan-Kettering Cancer Center followed 2606 patient for over 20 years after they underwent CSPY to remove polyps. The death rate from CRC was reduced by 53 percent in this cohort whose doctors removed adenomatous polyps compared with the expected death rate in the general population [29]. Since Medicare coverage of screening colonoscopies began in 2001, it has become the most used screening test in the United States [30].

CSPY does not come without limitations. About 10-20 percent of

colonoscopies fail to adequately examine the cecum [31, 32]. Complications such as bleeding and perforation can occur due to the invasive nature of the procedure. The risk of perforation is estimated at 1 in 1,000 cases but increases with age and the presence of diverticular disease [19]. Estimating sensitivity for CSPY can be challenging due to the lack of an independent gold standard. Researchers have used tandem colonoscopies and CT Colonography (CTC) studies (See Section B.1.e) to estimate the sensitivity of CSPY. Tandem CSPY examinations revealed miss-rates ranging from six to 12 percent for large adenomas and five percent for CRC [27]. In Pickhardt et al., 1233 study participants underwent CTC followed by same-day CSPY with segmental unblinding, which is a technique used to recheck CTC findings [33]. Colonoscopy, when compared to unblinded CTC studies, missed 12% of large adenomas and one of two cases of colon cancer [34]. These findings confirm that CSPY is not always accurate at diagnosing polyps and some may not detect all colon cancers.

B.1.d Double-contrast barium enema (DCBE). DCBE is a minimally invasive, moderately expensive radiological procedure that uses x-ray imaging to diagnose polyps and colon cancer. During the test, patients receive an enema with barium, followed by an injection of air. DCBE serves only as a diagnostic tool and offers no treatment option. Since no sedation is used, recovery time is relatively short. Similar to CSPY, DCBE examines the whole length of the colon but is less accurate. The recommended interval for DCBE is every five years. The sensitivity of a one-time test is around 48% for cancer or large polyps [35]. Studies examining its accuracy in asymptomatic populations are limited. Further, there are currently no published studies

that have examined its effectiveness in reducing incidence of or death from CRC. The use of DCBE has been slowly declining since the introduction of colonoscopy and CTC [36-38]. DCBE is a low-yield procedure for detecting polyps and is likely to be replaced by CTC due to the rising popularity of CTC and lack of availability of DCBE in the local ambulatory imaging center [37].

B.1.e CT colonography (CTC). CTC is an FDA-approved, minimally invasive screening test that takes a computed tomography (CT) scan –also called a CAT scan -- of the abdomen after the colon is filled with air. The bowel prep is similar to CSPY but, prior to the CT scan, the patient must also drink an oral contrast, which enhances polyp detection [39]. The examination takes about 30-60 minutes, requires no sedation and has a relatively short recovery time. The recommended repeat interval is five years after a normal CTC. CTC costs more than DCBE but less than CSPY and offers benefits over CSPY as an imaging tool. For example, in addition to its three-dimensional views, radiologists can refer back to two-dimensional views to identify important extracolonic or incidental findings during their reading. Extracolonic findings are common and 7% to 16% are of high clinical importance [40]. Although CSPY is widely accepted as the gold standard for CRC screening, CTC offers comparable results with respect to sensitivity and specificity. Results from two large clinical trials reported a per-patient sensitivity of more than 90% in detecting large adenomas (> 1 cm) [33, 34].

Although it has lower risk for perforation than CSPY, CTC is also not without risk. Adverse events include vasovagal reactions, prolonged cramping, and rare colonic perforations (0 to 6 per 10,000 CTC studies) [40]. Moreover, there is a

growing controversy over the long-term exposure to radiation from repeated CTC examinations. CTC delivers a radiation dose of 15 mSv, which is approximately three times what is delivered during mammography [41]. The estimated cancer risks are highly age-dependent, decreasing with age. According to Brenner, one CTC at age 50 increases the absolute lifetime risk of CRC by 0.044% compared to an increased risk of 0.022% at 70 [41]. This is of particular concern as the current recommendation requires patients to undergo a first CTC at 50 years of age and then, if normal, every five years thereafter. More studies are needed in this area to determine the long-term safety of periodic CRC screening using CTC.

B.2 CRC Screening Guidelines

Several professional societies currently publish recommendations for CRC screening, although these practice guidelines differ. These groups include the American Cancer Society (ACS), the US Preventive Services Task Force (USPSTF), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG). Efforts are being made to develop consensus guidelines for the use of CRC screening tests. Since 2006, the ACS, the American College of Radiology and the US Multi-Society Task Force on Colorectal Cancer (a consortium representing ACG, ASGE, AGA and ACP) have published consensus guidelines for the early detection of CRC and adenomatous polyps. The guidelines recommend the following options as acceptable screening choices for symptomatic adults aged 50 years and older:

- High-sensitivity FOBT annually, or

- FSIG every 5 years, or
- CSPY every 10 years, or
- DCBE every 5 years, or
- CTC every 5 years, or
- Fecal DNA at an unspecified interval

The USPSTF, however, issued a dissenting guideline in 2008 which concluded that "the evidence is insufficient to assess the benefits and harms of CTC and fecal DNA testing as screening modalities for colorectal cancer" [42]. DCBE was also removed from its 2002 guideline based on a recent publication that showed a low sensitivity (48%) for polyps larger than 10mm [43]. The updated guideline further recommended stopping screening in adults older than 75 years of age due to the decrease in life-years gained [3]. The USPSTF recommends one of following screening strategies for average-risk adults between ages 50 to 75 years:

- High sensitivity FOBT annually, or
- FSIG every 5 years, with FOBT every 3 years, or
- CSPY every 10 years

The American College of Physicians (ACP) also issued a new guideline for CRC screening in 2012. There are many similarities between the ACP guideline and that of the USPTF including its long list of recommended screening options and even the same testing intervals. But, the ACP guideline strongly recommends that physicians perform individualized assessment of risk for CRC and use shared decision-making with their patients in choosing a screening test that is best for them [44]. Further, the ACP recommends physicians to carefully consider patient preferences, availability of

the test and both benefits and harms of each screening option before making the decision [44].

These variations in clinical guidelines exist because there are differences in how professional organizations interpret and translate research findings based on scientific certainty, accuracy, benefit and safety. FOBT is the cheapest and least invasive test and it is also the only test for which there is direct evidence of effectiveness. CSPY may be more accurate, but it is the most expensive screening test and may involve significant out of pocket expense. Because it is the most invasive form of screening, CSPY is associated with side effects, albeit rarely. Despite the absence of direct evidence from a randomized, controlled trial demonstrating its effectiveness, there is a perception that CSPY is the gold standard. The evidence in support of CSPY is based on case-control studies, which provide weaker evidence than do randomized controlled trials. Experts generally agree that polyp removal by CSPY is the most effective way to prevent the development of colon cancer [16]. Results from the National Polyp Study support this expert opinion as mentioned above [29]. A randomized phase III clinical trial is also currently under way to compare neoplastic findings as assessed by screening CSPY to annual FOBT-directed CSPY [45]. Findings from the trial are likely to affect how experts view the effectiveness of CSPY.

B.3 Current Trends in the Use of CRC Screening Tests

The comparison of actual rates to recommended rates of CRC screening shows underuse, overuse and misuse patterns in addition to proper use [46]. Underuse is

failing to screen age-appropriate individuals (between 50-75 years) where the potential benefit of the procedure outweighs the risk. Reasons for underuse include lack of awareness among patients, physician recommendation and usual source of care [47-50]. Overall CRC screening rates are around 55%, which lags behind those of other screening procedures [30]. Overuse occurs when screening, particularly via costly procedures like colonoscopy, is performed where there may be more harm than good. Examples of overuse includes screening adults over 85 years old [3] and persons with severe co-morbid conditions [46] and performing post-polypectomy surveillance colonoscopies more aggressively than the guidelines recommend [51, 52]. Surveillance colonoscopies are repeat examinations performed following the identification and removal of adenomatous polyps to monitor recurrence. Misuse refers to poorly conducted colonoscopy or in-office FOBT, which are associated with high adverse events [53]. For the screening rates to be appropriate, a greater proportion of the healthy elderly population would need to undergo screening. The concept behind shared decision-making is that these variations in practice will be moderated and more closely match the guidelines when patients are involved in decision-making. However, further interventions are needed to minimize inappropriate use of screening and surveillance.

Shared decision-making is a two-way communication in which patients and physicians join in the process of decision-making. This cooperative process has been touted as a means to improve the quality of preference-sensitive decisions. There is evidence that patients' active involvement will help them make treatment decisions that reflect their values and preferences [14].

B.4 Barriers to Sharing Decision-Making in CRC Screening

The scientific uncertainty about outcomes in CRC screening as described above in Section B.1 makes these services preference-sensitive, which refers to services governed by strong medical theory but where medical evidence is variable for two or more alternative treatment strategies [4]. The work of John Wennberg highlighted geographic variation in the use of preference-sensitive services as early as the 1970s [4]. Recent Medicare claims data confirmed his findings that the use of FOBT and CSPY tests is highest in the northeast and southern parts of the United States [54]. Variation in use of these preference-sensitive procedures were thought to be associated with the differences in local practice patterns of physicians [4]. Shared decision-making has been advocated to reduce these unwarranted clinical practice variations while increasing patient involvement in decision-making. However, physician, patient and system characteristics have posed challenges to adopting a shared decision-making model in CRC screening [55-59].

There are many physician-related barriers to promoting shared decision-making in CRC screening. Clinical practice guidelines have been established as previously discussed (See Section B.2), but physicians have long resisted guidelines, mostly due to lack of awareness, familiarity and agreement with the guidelines [57]. Physicians, the principal source of health-related information for patients, do not always present information in a balanced and unbiased manner. A nationwide survey of nine common medical decisions found that physicians are more likely to emphasize the benefits than the risks of screening [58]. Physicians are less likely to communicate

scientific probabilities when they perceive that patients will experience difficulty understanding them [59]. Communicating risk and uncertainty not only fulfill legal and ethical obligations of informed consent but also help create realistic expectations for patients. These survey findings confirm previous studies showing that many medical decisions do not meet the standard for shared decision-making [55, 56]. Promoting measures to encourage shared decision making in CRC screening allows patients to be screened in a manner consistent with their preferences and wishes [13, 60-65].

Patient characteristics also make shared decision-making challenging. Patients may have co-morbidities that make it difficult to be screened in a manner consistent with their wishes. More importantly, some patients have low literacy [66], low health literacy [67] or low numeracy [68], all of which compromise the delivery of effective health care. Health literacy as defined by the Institute of Medicine is the ability to obtain, interpret and understand basic health information [69]. This includes the capacity to read and interpret written medical instructions as well as the ability to use and reason with numbers (numeracy). Deficiencies in these areas have been associated with adverse health outcomes such as lower utilization of screening and preventive services [70, 71]. Both health literacy and numeracy are important issues in shared decision-making because patients must have sufficient reading and computational skills to interpret quantitative information. These functional skills are imperative in CRC screening because they enable patients to accurately interpret the risks and benefits of different screening tests. A study examining cancer patients' perceptions of the benefits of participating in Phase I clinical trials found that patients who

incorrectly answered the numeracy question had higher expectations of benefit from experimental therapy than those who answered it correctly [72]. The findings have important implication for patients who are faced with screening decisions because patients with low numeracy skills have difficulty comparing the benefits and risks of different screening tests.

While there is considerable interest in promoting shared decision-making in clinical practice, overall use is limited due to system barriers. Clinic visits are short and physicians are often tasked to address multiple problems in addition to preventive services during the visit. It is estimated that it would take physicians 7.4 hours a day to address all recommended preventive services [73]. In addition to lack of time, there are no payment incentives to encourage patients and physicians to engage in shared decision-making [74]. Further, misaligned financial incentives and reimbursement have resulted in poor quality of care by steering patients and physicians to more costly procedures that may have a greater financial return for physicians. Even well-intentioned legislation can result in unintended consequences in health care. Since Medicare coverage of CSPY began in 2001, the proportion of people who were up to date with CRC screening by CSPY more than doubled by 2007 while the proportion of people who were up to date by FOBT or FSIG decreased significantly [75]. Moreover, the National Survey of Primary Care Physicians reported that in 2007, the majority of primary care physicians recommended CSPY while fewer primary care physicians routinely recommended FOBT, FSIG or DCBE [76]. Taken together, these findings highlight many of the existing system barriers that discourage shared decision-making in health care.

B.5 Facilitators for Shared Decision-Making in CRC Screening

Factors that appear to facilitate shared decision-making relate to the availability and use of quality decision aids in clinical practice. Since the first decision aid was introduced in 1983, a great deal of progress has been made in the infrastructure to foster shared decision-making. The Cochrane Collaboration Patient Decision Aid Review Group created a comprehensive inventory of patient decision aids, currently consisting of over 500 decision aids [77]. Until 2003, the quality of these decision aids varied widely. Some decision aids were biased and others did not cite evidence sources. Beginning in 2003, international efforts were made to bring greater transparency to the development and evaluation of decision aids. Over 100 researchers, practitioners, patients and policymakers from fourteen countries participated in online voting to establish the International Patient Decision Aid Standards (IPDAS), a set of criteria for measuring the quality and effectiveness of decision aids (See Table 2) [78]. The IPDAS collaboration also resulted in an instrument (IPDASi) to measure the quality of patient decision aids in ten dimensions [78]:

(1) Providing information

(2) Presenting probabilities

(3) Clarifying values

(4) Providing guidance on deliberation and communication

(5) Resulting from a systematic development process

(6) Using up-to-date evidence

(7) Disclosing of conflict of interest

(8) Using plain language

(9) Evaluating the quality of decision

(10) Testing

A study validated that IPDASi has the ability to assess the quality of decision aids [79].

B.6 The Ottawa Decision Support Framework

This framework is an evidence-based theory used to guide patients and practitioners through health-related decision-making. The framework is derived from expectancy value, decisional conflict, and social support theories [80-87]. The framework has been developed to guide patients and physicians in health decisions that are perceived as value-sensitive, including colon cancer screening decisions. Addressing decisional needs and providing the necessary decisional support through decision aids, coaching or counseling can work to improve decisional quality. The framework asserts that there are three major components that contribute to making a health care treatment decision: decisional needs, decision quality and decision support. It uses a three-step process as follows [88]:

First, *decisional needs* must be identified through baseline assessment of important factors related to decision-making (Box #1). A simple self-administered questionnaire can be provided prior to introducing the decision aid to determine the level of understanding of facts about the disease, unrealistic expectations, and uncertainty about participants' own personal values or lack of support and resources,

all of which are barriers to making a good-quality decision. Second, the use of *decision support* is advocated to assist participants in decision-making by clarifying their decision, needs, and values (Box #2). Some suggestions for clarifying decisions are to ask participants to rate the importance they attach to possible health outcomes (e.g. risks, benefits and tradeoffs). According to one study, patients who received a decision aid with a weigh-scale exercise (e.g. guidance and coaching) had better congruence between their values and choices compared with those who were given a decision aid that simply asked them to consider the personal importance of benefits versus the risks [89]. Patient testimonials, both positive and negative, are also increasingly used in decision aids because they are thought to help participants judge the likelihood of each outcome [90, 91]. Inclusion of patient testimonials, when presented in an unbiased manner, is important to effective decision-making and has been shown to significantly affect treatment choices [92]. Using numbers to illustrate probabilities of risks in decision aids can further improve the quality of decision-making by creating more realistic expectations for participants [88, 93].

Finally, the assessment of decisional quality is imperative in ascertaining the success of the decision support and decision-making process (Box #3). The quality of a values-based decision is often difficult to assess due to its subjective nature. However, the framework proposes that decisional quality is a measure of the extent to which the patient's choice is "informed, consistent with personal values and acted upon" [88]. As a result, supporting decisional needs of individual patients is the first step to ensuring high quality decision-making. In summary, quality decisions can result when decisional needs are adequately addressed and proper decision support is

provided at the point of decision-making.

The dissertation applied the above framework in designing the study. To address decisional needs of the patients faced with screening decisions, a quality decision aid (based on IPDASi) was used to provide information about options and outcome probabilities and to clarify values that matter most to patients. To determine whether the decision aid was effective, the investigator used the Decisional Quality Instrument (DQI) to measure knowledge and the extent to which patients' screening choice matched their values and preferences.

B.7 Decision Aids and Their Effect on Decisional Quality

A decision aid should be carefully crafted and balanced to include all benefits and risks of all effective screening options without endorsing any particular option. Decision aid content is highly variable and depends heavily on what effective screening tests are available. One of the benefits of using a well-crafted decision aid is that it balances any bias in health related decision-making. CRC decision aids used in previous studies are currently either outdated or do not provide up-to-date information on available screening options [5-10, 12, 94].

The colorectal cancer decision aid (CRCDA) entitled, "Colon Cancer Screening: Deciding What's Right for You," was specifically written to guide CRC decisions about current screening techniques. It comes in DVD format with a pamphlet; the video program lasts approximately 30 minutes. The CRCDA (Version CRC001B V03) includes up-to-date information on FOBT, FSIG, combination of FOBT and FSIG, CSPY and CTC. It was developed by the Foundation for Informed

Medical Decision Making, a non-profit organization based in Boston, Massachusetts, whose mission is to support shared decision-making by developing and evaluating decision support tools. According to the international standards of quality for decision aids (See Table 2) [95], the CRCDA is one of the most highly rated colon cancer screening decision aids and has been included in the Cochrane Decision Aid Registry, one of the best evaluated libraries of quality decision aids. The CRCDA screening includes up-to-date information on screening options based on the latest evidence, providing patients with the opportunity to choose an option most consistent with their values.

Decision aids are commonly used to both disseminate important scientific findings and to support patient involvement in medical decision-making. Several systematic reviews on decision aids have been published in the recent past [77, 96-98]. Decision aids in most studies have been developed to assist treatment decisions of patients with cardiovascular disease [99-102], benign prostate disease [103, 104], menopause [88, 105, 106] and cancer [5-9, 12, 94, 107-131]. In general, studies have found that decision aids improve patient knowledge [88, 102, 107, 111, 129, 130], increase realistic expectations [106, 112, 132], reduce decisional conflict [88, 105, 106], increase satisfaction with decision-making [133] and increase active participation in decision-making [134]. Studies have also examined the effects of decision aids on CRC-specific knowledge [12], decision process [5], test completion [135, 136] screening preferences [6, 7, 9, 10, 94, 135], treatment undergone and screening intentions [8]. However, of these studies, only five were conducted using a randomized controlled design as outlined in Table 3. The current study is the first to

examine the effectiveness of the CRCDA in a clinical setting using the quality of colon cancer screening decisions as the indicator for effectiveness.

Colon cancer screening decisions should reflect not only clinical guidelines but also patients' values and preferences for screening since there is clinical uncertainty and lack of agreement on the best course of action. The definition of a quality decision commonly endorsed by supporters of shared decision-making is that it should be "informed, consistent with personal values, and acted upon" [88]. Toward this end, health decision researchers like Sepucha and Mulley have proposed a framework for measuring decision quality to assess the effectiveness of decision aids and their impact on the decision-making process [63]. According to this framework, a valid and reliable assessment of decision quality encompasses three separate components: decision-specific knowledge, values for the salient outcomes and treatments chosen [13, 63, 64].

Two well-validated surveys commonly used to measure decision quality are the Decisional Conflict Scale (DCS) and the Satisfaction with Decision Scale (SWD). Decreased decisional conflict and increased satisfaction with decision-making have been traditionally associated with quality decision-making. The DCS is often used to measure a patients' level of uncertainty when making health care decisions while the SWD Scale is designed to measure satisfaction with health care-related decisions. High scores on the SWD Scale, which indicate higher satisfaction with a decision, also correlate with decisional certainty [133].

There are several limitations associated with these instruments, as outlined by Sepucha [63]. First, patients often do not have the expertise to properly evaluate the

technical aspects of the care delivered when they are asked to indicate whether they were adequately informed, knew the benefits and risks of each option and made an informed choice. Also, patient satisfaction is related to expectations being met; patients with lower expectations are more likely to report higher satisfaction with care [137]. Second, although a low decisional conflict score has been touted as a desirable effect of decision aids, Nelson argues that decisional conflict may be a byproduct of an ongoing decision-making process that gives proper considerations to all possible alternative outcomes [138]. The controversy over these two well-validated surveys points to the need for a more reliable measure of decisional quality.

Decision quality instruments have been previously developed for breast cancer, benign prostate disease and a set of symptom-driven conditions (e.g. hip and knee osteoarthritis, herniated disc and spinal stenosis) [13, 64, 139]. Each of these instruments was developed through extensive literature review, interviews with patients and physicians and field-testing. However, the effects of decision aids on the quality of CRC screening decisions are largely unknown. Karen Sepucha is currently in the final stages of developing a DQI for colon cancer screening. The instrument has just been through its final round of field-testing but has yet to be tested in a clinical environment. To further understand whether patients' colon cancer screening decisions reflect their preferences and values, the DQI for colon cancer screening decisions should be validated in a large clinical trial.

B.7.a Test of knowledge. The first aim of this project was to determine whether exposure to the decision aid results in improved knowledge about colon cancer. Sepucha and Mulley propose that there is a set of facts that is considered

critical to making an informed decision. First, improved knowledge is an important building block of decisional quality as well as the goal of any decision aid. As many as 51 of 86 studies from a Cochrane Review assessed the effects of decision aids on knowledge, showing a trend toward higher knowledge scores [14]. However, to date, no valid, systematic approach to measuring informed decision-making has been adopted. Previous studies that used investigator-developed knowledge tests [5, 12] failed to obtain input from various stakeholders when developing the instrument. Instead, Sepucha advocates "a rigorous social process" involving extensive literature review and stakeholder surveys of a multidisciplinary group of providers and a group of patients to verify the accuracy, importance and completeness of tested facts [77]. Further, in order to compare decisional quality across different studies for the same condition, it is important to test for a common set of knowledge that addresses issues that are salient for a given condition. This project used the DQI developed by Sepucha using this rigorous, systematic approach.

B.7.b Value concordance. The second aim of the study was to examine value concordance. In preference-sensitive decisions, ideal decisions happen when patients' preferences match their treatment choice. The extent to which patient preferences match treatment choice has been studied in benign prostatic hyperplasia [104], breast cancer [13, 140] and hormone replacement therapy [141]. Barry's 1995 study examined decisions about treatment of benign prostate hyperplasia and provided strong support for considering patient preferences [104]. Men who were bothered by symptoms were more likely to have surgery than those who did not, while those who felt strongly about preserving their sexual function were less likely to have surgery

[104]. Similar findings have been reported among breast cancer survivors: women who preferred to "keep breast" were more likely to have breast conserving therapy while those who preferred to "avoid radiation" were more likely to choose mastectomy [13]. Moreover, in a 2004 study of women age 67 or older with early stage breast cancer, those who received treatment consistent with their preferences reported better body image [140]. These studies suggest that high value concordance is critical to quality decision-making.

A review of 86 randomized clinical trials of patient decision aids indicated a wide range of measures used to evaluate effectiveness [14]. Studies specifically examining the quality of colon cancer screening decisions have also demonstrated the lack of consensus in the selection of primary and secondary outcomes, as noted in Table 3 [5-10, 12, 94, 135, 136, 142]. Due to the limitations of currently available instruments as previously described, a new measure of decisional quality has been recommended. The new instrument measures decisional quality in CRC screening and specifically assesses (1) CRC-specific knowledge (2) values that are salient for colon cancer screening outcome and (3) screening strategy chosen [63].

Only five other studies have examined effectiveness of a decision aid on colon cancer screening decisions using a randomized controlled design (See Table 3). Measures these studies used to demonstrate the effectiveness of colon cancer screening decision aids were knowledge [5, 12], screening intention or interest [10], test ordering [8] and completion rate [8, 135, 136]. No previous CRC study has measured decisional quality based on knowledge, values and screening choice.

This dissertation represents the first study to examine the quality of CRC

screening decisions in a primary care setting. Using a randomized controlled design, this study compared knowledge about CRC and value concordance between the control and the intervention group. The control group was educated about CRC and various screening options during the usual physician counseling. The intervention group, in addition to physician counseling, received a decision aid to take home. Both groups received and self-administered a DQI questionnaire, which they took home and returned by mail. This dissertation used two innovative strategies to address the specific aims (See Section A). First, a highly-rated decision aid was used to educate patients about the benefits and risks of screening options that have been endorsed by the latest guidelines. Second, a new measure of decisional quality was used to measure knowledge and value concordance with the choice of screening test. This study has public health significance in that it will provide insight into whether decision aids should become a routine part of making CRC decisions and establish the degree to which they improve decision quality.

C. Methods and Materials

C.1 Study Design

This prospective, randomized intervention trial examined the effect of an educational intervention on colorectal cancer (CRC) screening decisions in a for-profit medical practice. The intervention group received a packet containing the decision aid and the Decisional Quality Instrument (DQI), a survey (described in the Measures section below) developed by Sepucha to assess participants' knowledge of CRC and the various screening options and to measure the extent to which their preferences match their chosen procedure. The control group received usual care and the DQI alone (without the decision aid). Participants were instructed to view the decision aid and/or complete the DQI survey at home.

C.2 Study Site

The study was conducted in the internal medicine clinic at the George Washington Medical Faculty Associates (MFA) – the largest independent physician group in the National Capital Area, with locations downtown in the District of Columbia and in Georgetown, Upper Northwest Washington; Bethesda, Maryland; and Reston, Virginia. MFA's 700 physicians in 51 medical and surgical specialties manage more than one million patient visits each year.

The study was undertaken to assess the feasibility of implementing a CRC screening decision aid at a busy clinical practice and to examine its effect on the quality of CRC screening. MFA physicians offer a wide range of CRC services as part of its health maintenance visit including fecal occult blood test (FOBT), flexible

sigmoidoscopy (FSIG), combination of FOBT and FSIG, colonoscopy (CSPY) and CT colonography (CTC). Although educating patients about risks, benefits and tradeoffs of different screening options is a routine MFA practice when discussing the importance of CRC screening, the use of a decision aid is not part of standard care. All study activities were approved through the George Washington University and Uniformed Services University Institutional Review Boards.

C.3 Study Population

The study population consisted of volunteers eligible to receive CRC screening at MFA during the recruitment period from May through October 2011.

C.3.a Inclusion criteria. Adults between 50 and 80 years of age with an average risk of CRC made up the primary study group, since this is the target audience for the decision aid. Individuals considered to be at average risk for CRC are those whose only risk factor is their age [3].

C.3.b Exclusion Criteria. High-risk individuals were excluded from the study. Individuals may be at increased risk for CRC due to a history of precancerous polyps, a personal history of CRC, a family history of CRC or adenomatous polyps in a first-degree relative before age 60 years or a history of inflammatory bowel disease [143]. Volunteers with the following contraindications were also excluded:

- Positive guaiac-based test of stool within 6 months before referral
- Iron-deficiency anemia within previous 6 months
- Rectal bleeding or hematochezia within previous 12 months
- Unintentional weight loss of more than 10 lbs within previous 12 months

- History of adenomatous polyps, colorectal cancer, or inflammatory bowel disease
- History of familial adenomatous polyposis or hereditary nonpolyposis cancer syndromes
- Colonoscopy or flexible sigmoidoscopy within previous 5 years
- Barium enema or CT colonography within previous 5 years
- Pregnancy

Patients who met the eligibility criteria for CRC screening were recruited for the study regardless of race, gender and ethnic origin. Neither women nor minorities were excluded. Since CRC screening is aimed at adults over the age of 40, no children were invited to participate in the study.

C.4 Procedures

C.4.a Recruitment. The investigator performed chart reviews of patients to be seen in the Clinic one week prior to the scheduled appointment, carefully identifying individuals who might be eligible for participation in the study. Chart reviews were done using Allscripts, MFA'S HIPAA compliant electronic medical record, on all individuals regardless of their chief complaints. Recruitment was thus not limited to those coming in specifically for CRC screening (i.e., patients were also being seen for routine physical examination or for known diagnoses such as hypertension, diabetes, weight management, seasonal cold, asthma etc). On the day of the appointment, the investigator obtained permission from providers and then approached eligible patients and asked them to enroll. If they agreed they were asked to remain in the clinic following their physician visit to be placed into the study. After the physician met with

the patient as scheduled, the investigator initiated the recruitment process, talking with the volunteer in the examining room. The investigator provided the volunteer a brief description regarding the nature of the study and asked for permission to speak about the study. If the volunteer consented, the investigator then completed the Inclusion & Exclusion Criteria Checklist (See Appendix F.1) to confirm their eligibility for the study. Volunteers meeting the eligibility criteria were then invited to join the study.

C.4.b Consent process. The investigator obtained written consent and HIPAA authorization prior to randomization and data collection. In order to promote the volunteers' understanding of the study, consent documents were written clearly, using non-technical and non-medical terms, and were written at the sixth to eighth grade reading level. Volunteers were provided with ample time to review all consent documents and the investigator was present to answer questions about the study. If a volunteer had medical questions after reading the consent form, he or she met with an MFA healthcare provider with the knowledge and expertise to address those questions. The investigator asked volunteers to sign and date the consent form only after they had sufficient time to review the consent documents and had all of their questions answered. Volunteers who were either ineligible or declined to participate in the study received care as planned with their provider. The consent process took on average 10 to 15 minutes. Every attempt was made to avoid disruption to clinic flow. Clinical processes took precedence; if interrupted, the investigator finished the recruitment/consent process later.

C.4.c Enrollment and randomization. After consenting, participants completed Data Collection Form #1, which was self-administered (See Appendix F.2).

All Data Collection Forms were checked for completeness. If a questionnaire contained blanks, the investigator asked the participant to provide the missing data.

Participants were randomized to one of the two cohorts using a sealed envelope system. Prior to the beginning of the study, the investigator prepared 280 identical envelopes, half containing a card indicating "decision aid" and half containing a card indicating "usual care." These cards were shuffled and then numbered sequentially. After signing the consent document, each participant was assigned a study number and given the corresponding envelope. Each participant was thus randomly assigned to usual care or the educational intervention based on the card in his or her sealed envelope.

Blinding of participants was not possible in this study: immediately following the randomization, participants either received the Colorectal Cancer Decision Aid (CRCDA) or proceeded through the usual decision process. No specific attention was given to notifying providers about an individual participant's randomization status, but participants were not prohibited from sharing their status. The intervention group received the packet containing the CRCDA and the DQI survey. Meanwhile, the control group received the DQI alone without the CRCDA. Participants were instructed to view the CRCDA and/or complete the DQI survey at home. They were also instructed to return the completed survey in a pre-paid envelope provided by the investigator. All participants received compensation in the amount of $5 at the time of enrollment and a $10 gift card upon returning the completed final survey. The financial support for this study came from the Foundation for Informed Medical Decision Making (FIMDM).

C.4.d Educational intervention. The CRCDA was developed by FIMDM to educate patients about colon cancer and the various screening tests currently available. FIMDM is a non-profit organization whose mission is to support shared decision-making through developing and evaluating decision aids. As explained in Section B.5, the CRCDA packet, entitled "Colon Cancer Screening: Deciding What's Right for You," consists of a DVD and an accompanying pamphlet. The CRCDA helps patients with their colon cancer screening decisions by providing information about options in a balanced manner, presenting probabilities of certain outcomes (i.e. risks and benefits), clarifying and expressing personal values involved in the decision, using patient stories, and providing the latest evidence about outcomes of different screening options. The video lasts 30 minutes and introduces all five screening options: FOBT, FSIG, a combination of both, CSPY and CTC. The CRCDA is one of the highest rated aids available according to the International Patient Decision Aid Standard (IPDAS) criteria [78, 95] (See Section B.5). The Cochrane Decision Aid Registry has also evaluated it and determined that it meets the minimum criteria for inclusion in its registry. FIMDM's decision aids remain up-to-date because they are subject to biannual external review by clinicians and patients not associated with the Foundation. FIMDM provided the investigator with written permission to use the CRCDA.

C.4.e Decisional Quality Instrument. The measures included in the DQI are described in the next section. Participants took the DQI home to complete; participants in the intervention group were instructed to complete it after watching the CRCDA DVD and reading the pamphlet. Participants returned the survey to the investigator in a pre-paid envelope. Each participant had up to two weeks after the initial visit to

complete and return the survey forms. Every effort was made to minimize the likelihood of response bias or non-response error. Up to three attempts were made to reach non-responders by phone. To avoid coercion, however, the investigator held no more than one actual phone conversation with each nonresponder, encouraging him or her to complete and return the survey form. If the investigator was unable to reach the non-responder by phone after three attempts, or if the participant did not return the survey after the phone conversation, he or she was considered lost to follow-up. However, the investigator sent out a final reminder, via follow-up letter, to each of those participants approximately two weeks after the last reminder call.

Upon receipt of each survey, the investigator entered the data into an Access database and reviewed the entered data for accuracy. All data entries were double-checked for accuracy. Participants with missing data were not contacted to avoid introducing bias by only collecting missing data from those respondents who were available by phone. Survey forms were stored in a locked cabinet and the Access database was kept on a password-protected computer that was accessible only by the investigator. No identifiers were stored in the database. Identifiers, which were linked to participants' names, were kept separately in a log inside a locked cabinet along with the survey forms.

C.5 Measures

Participants provided data at two separate collection points. The first data collection took place on the date of enrollment at baseline at the time of randomization after the informed consent was obtained. Participants self-

administered Data Collection Form #1 (See Appendix F.2), which included demographic questions. Second, participants self-administered Data Collection Form #2 (See Appendix F.3) and the DQI (See Appendix F.4) at home and returned them via mail in a return envelope provided by the investigator. Data Collection Form #2 assessed participants' screening choice and their involvement with the decision aid (in the intervention arm).

The following data were collected for the purpose of the study:

C.5.a Patient demographics. Participants' self-reported age, height, weight, education, race, marital status, employment status, income, social history and perceived health-status on Data Collection Form #1 (See Appendix F.2). Participants were also asked about where and how they obtain health-related information.

C.5.b Intervention participation. The completion of the decision aid was assessed on Data Collection Form #2, which was self-administered at the participant's home and returned to the investigator via mail. Participants' completion of the DVD was measured by asking whether they viewed at least 50% of the video or less than 50% of the video [144]. Participants in the intervention group who viewed at least 50% of the video were categorized as "viewers" while those who viewed less than 50% were categorized as "non-viewers" [144, 145]. Similarly, participants who reported reading some or all parts of the pamphlet were categorized as "readers" while those who did not were categorized as "non-readers".

C.5.c Decisional Quality Instrument (See Appendix F.4). The quality of CRC screening decisions was assessed using the Decisional Quality Instrument (DQI), which is in the final phase of refinement. The development process for the DQI,

similar to the development of instruments for breast cancer and symptom-driven conditions, has been described elsewhere [13, 64, 146]. The investigator obtained written permission to use the instrument. There are three main parts to the instrument:

Knowledge: There were a total of sixteen questions: fourteen multiple-choice questions and two open-ended questions. The multiple-choice questions measured respondents' knowledge about CRC as well as the benefits and risks of various screening options. The open-ended questions allowed patients to estimate the incidence and mortality associated with CRC.

Value: Ten value items were included to examine personal values or importance ratings of key screening attributes. Respondents scored these items on a 10-point likert scale from 0 = (not at all important) to 10 = (extremely important). Items included the following ten screening goals and concerns:

1) Finding colon cancer early
2) Knowing whether or not the respondent has colon cancer
3) Choosing a test that doesn't need to be done every year
4) Choosing a test where sedation is not used
5) Choosing a test that doesn't cost a lot of money
6) Avoiding a test that requires handling of stool
7) Avoiding a test that may be painful
8) Avoiding a test where a tube is put into the rectum to look inside the colon
9) Avoiding a test that can cause bleeding or a tear in the colon
10) Avoiding a test where you have to drink a liquid before the test to clean out the colon

Additionally, participants were asked to identify and rank their top three CRC screening goals and concerns. All participants were asked to complete the DQI survey regardless of which study group they were in. The survey was administered on paper in the participant's home.

Screening decision: Ten items on Data Collection Form #2 (See Appendix F.3) assessed whether the participant discussed various screening options with a health professional and whether the health professional ever recommended any specific screening test(s). Participants were also asked to report whether they had previously undergone a test for colon cancer and, if so, how much the participant was previously involved in making the decision and what elements of the decision were made by a physician and/or other health professional.

C.5.d Screening choice. One multiple-choice item on Data Collection Form #2 (See Appendix F.3) captured the participants' preferred method of screening, which might be any of the five available colon cancer screening methods named above. The survey asked participants to select their preferred method of screening from a list and provide their reason(s) for their choice. The purpose of this question was to determine whether the participant's choice of screening method was consistent with the values and preferences he or she had provided elsewhere in the survey.

C.6 Statistical Consideration

C.6.a Outcome variables. The primary endpoint of this study was knowledge about colon cancer screening. The secondary endpoint was concordance between participants' individual values and screening choice. Knowledge and value

concordance scores were compared between the intervention group and control group to assess the effect of the CRCDA.

C.6.b Data analysis.

1) Descriptive statistics (mean/standard deviation or frequency/percent) were used to describe demographic characteristics and prior screening history of the intervention group and the control group. Chi-square tests were used to determine whether there were differences between the study arms and screening decision groups with regard to gender, education, marital status, income, smoking, drinking and health status. T-tests were used to determine group differences (between the study arms and screening decision) with regard to age and body mass index.

2) Involvement with decision-making: Differences between the groups in the frequency of discussion about various screening options and their associated benefits and risks were assessed using chi-square tests.

3) Decision-specific knowledge scores (Specific Aim 1): To determine whether the use of the CRCDA increased participants' understanding of colon cancer and the different screening options, knowledge scores were calculated and compared across the two groups. The knowledge test was graded according to the answer key provided by Dr. Sepucha (See Appendix F.5). The knowledge score was calculated as the total number of correct responses divided by the total number of questions and was reported as a score from 0 to 100%.[1] Each correct item received one point. Items with

1 The open-ended questions were graded using a rubric supplied by the developer; a 'correct' answer for question 3.5 was any number between 4 and 10 and for question 3.16 any number between 1 and 5.

multiple parts also received one point but the point was evenly distributed among the subparts. For example, if an item had four subparts, each correct subpart received 0.25 of a point. A missing response was scored as incorrect. Surveys with more than eight missing responses were not used in the analysis.

Descriptive and bivariate analyses were conducted to assess the distribution of knowledge scores and to compare the mean scores of the two study groups. Chi-square tests were used to compare the percentage of correct answers between the intervention and the control group. In sub-analysis, mean knowledge scores were stratified by education (college graduation vs. no college education). Incorrect responses to the open-ended questions were further examined to assess whether respondents overestimated the risk of being diagnosed with CRC and the risk of dying from CRC.[2] Univariate regression was performed to adjust for covariates associated with knowledge score at $p < 0.05$ level.

To account for non-participation in the intervention group, two different analyses were performed. An intent-to-treat analysis (ITT) was used to evaluate the overall effectiveness of the CRCDA on knowledge. To examine the effect of simply providing the DVD, all respondents were included in the analysis, regardless of whether they adhered to the assigned intervention. The per protocol analysis (PP) was then performed to assess the effect of the CRCDA on knowledge when participants adhered to the protocol. The per-protocol analysis restricted the intervention group to respondents who reported viewing at least half the DVD (See *C.5.a)*. The reason for dichotomizing on the basis of percent viewing was that the

2 Responses greater than 17 for question 3.5 and greater than 8 for question 3.16 were considered overestimating by three-fold or more.

majority of the participants (88%) in the intervention group reported watching at least half the video. A large portion of these respondents (66%) reported both watching half the video and reading some parts of the pamphlet.

4) *Value concordance (Specific Aim 2)*: Value concordance was assessed using both intent-to-treat and per-protocol analyses as previously described (See Section C.6.b). For value concordance analyses, screening decisions were dichotomized since CSPY and FOBT represented screening preferences for more than three-quarters of the respondents. Respondents who chose CSPY were classified as having preference for CSPY while all others were classified as not having preference for CSPY. The same technique was used to classify participants as having preference for FOBT or not having preference for FOBT.

Univariate logistic regression was initially used to examine the association between respondent characteristics and their preference for CSPY. Respondent characteristics with univariate p values of 0.05 or lower were entered into the multivariate logistic model to predict preference for CSPY.

The extent to which respondents' values matched their preference for CSPY was examined using multivariate logistic regression. The purpose of this analysis is to establish whether value ratings on a scale of 1 to 10 can explain preference for CSPY. The multivariate model predicted choosing CSPY using importance ratings and the study arm. A value rating*intervention interaction term, was also added to examine whether the intervention modified the association between importance ratings and screening choice, testing the hypothesis that the association between a given value and a concordant choice would be stronger in the intervention group

than in the control group.

Percent match procedures were also used to examine values concordance for CSPY as previously used [147, 148]. First, the individual value items were examined in univariate analysis by comparing the mean value items between respondents who preferred CSPY and those who did not prefer CSPY. Univariate logistic regression was also used to calculate individual concordance score, which measured the extent to which participants' individual values matched their choice of CRC screening test. The purpose of this analysis was to establish whether value items on a scale of one to ten could explain preference for CSPY. Respondents who reported preference for CSPY who also had predicted model probabilities greater than or equal to 0.5 and respondents who did not prefer CSPY who also had predicted model probabilities less than 0.5 were considered to have value concordance. The study then compared the percent of each of the intervention and control groups with value concordance. In SAS, CTABLE PPROB=0.5 option in logistic regression offers summary concordance scores for each value item with a predictability at 0.5. The summary concordance score provided the percentages of people whose decisions matched their goals and concerns of CRC screening as predicted by the regression model.

Screening preference for FOBT was dichotomized such that respondents who chose FOBT were classified as having preference for FOBT while all others were classified as not having preference for FOBT. Low preference for FOBT in both the intervention (10%) and the control group (14%) resulted in limited data for analysis. Mean value ratings were compared between the intervention and the

control group respondents with respect to respondents' preference for FOBT both in ITT and PP analyses.

5) *Exploratory analysis to determine predictors of choosing CSPY*

A multivariate logistic regression model was developed to determine which of the ten value item variables contributed significantly to predicting the preference for CSPY, using methodology previously described for breast cancer decisions [149]. The goals and concerns that were significant at the 0.05 level on multivariate analysis were included in the final model to predict choosing CSPY. An overall summary concordance score was calculated for the final model using the same approach previously described (See data analysis for Specific aim #2). Two screening goals, "finding colon cancer or polyps early" and "knowing whether or not you have colon cancer" were highly correlated and did not contribute significantly to the multivariate model ($r = 0.71$, $p < 0.0001$). The fact that these variables were highly correlated provided the basis for eliminating one of the variables from the multivariate analysis. Spearman's correlation test was used to measure the strength of relationship between these values and the outcome. The value of "knowing whether or not you have cancer" ($r = 0.21$, <0.003) was dropped from the multivariate analysis because the value of "finding colon cancer or polyps early" ($r = 0.27$, $p < 0.0001$) was more closely associated with the outcome. The goals and concerns that were significant at the 0.05 level on multivariate analysis were included in the final model to predict choosing CSPY.

C.7 Sample Size Calculation

In this study, the primary hypothesis is that the use of a decision aid increases the knowledge score in the educated cohort compared with the usual care group. Meade's study found that there were significant differences between the pretest and the posttest mean scores in the educational intervention group [12]. A sample size of 100 in each group was estimated to have 80% power to detect a difference in means of 0.80 assuming that the common standard deviation was 2.0 using a two group t-test with a 0.050 two-sided significance level. This was a smaller effect size than that observed by Meade et al ($\delta = 1.55$) and corresponded to a "medium" effect size of 0.4 standard deviations. We proposed this sample size to allow for the possibility of observing a medium rather than large effect and to allow for the additional power required for the regression models in specific aim #2. In logistic regression it is desirable to have at least 10 events per independent variable in the model [150]. For multinomial logistic regression we first considered the number of patients who chose the least popular screening choice. We expected a model with five independent variables (importance rating, intervention, interaction and two demographic variables), which means each screening choice would have to been selected by at least 50 patients. If the least common choice was selected by one-fourth of patients, then the total sample size should be $4 \times 50 = 200$. Additionally, in order to account for loss to follow up and non-adherence to the protocol, additional subjects were added to increase the sample size by 40% in each group. Total requested sample size was 280.

All data analyses were done in SAS 9.1.3 for Windows.

D. Results

D.1 Participant Baseline Demographics

The detailed recruitment process is shown in Figure 2. In consultation with George Washington Medical Faculty Associates (MFA) physicians, the student investigator identified 307 potentially eligible patients between May 17, 2011 and October 28, 2011 at MFA. All volunteers were screened and 280 patients agreed to participate. These 280 participants were randomly allocated to the two arms of the study; 140 received the decision aid and 140 served as controls. Of 307 potentially eligible patients, 27 (8.8%) either didn't meet the eligibility criteria or declined to participate. Reasons for not participating in the study were mostly reported lack of time or problems with parts of the informed consent document. In the intervention group, 93 (69%) returned the completed survey, while the response rate for the control group was substantially higher at 114 (84%). A total of nine participants were disenrolled from the study: Seven participants were dropped from the study after they returned the survey because, on close inspection, it was discovered that a first degree relative had been diagnosed with CRC before the age of 60. Two additional participants, one from the intervention group and one from the control group, voluntarily disenrolled from the study without giving reasons to the investigator.

Table 4 shows demographic characteristics of all participants collected at baseline. The mean age of participants was 60 years and the mean Body Mass Index (BMI) was 31. Educationally, 2.2% in the intervention group and 3.8% in the control group did not complete high school; roughly half of all participants (51%) completed a college degree. All baseline characteristics were similar between two groups with the

exception of employment status and income. Participants in the intervention group were more likely to be currently employed ($p < 0.001$) and less likely to have missing data for income. The majority of study participants self-rated their health as excellent, very good or good. Response rates were lower in the intervention group (69%) compared with the control group (84%). This difference is most likely due the fact that the intervention group was asked to watch the DVD and read the accompanying pamphlet before completing the survey.

D.2 Respondent Characteristics and Results

More than three-quarters of all participants (76%) returned the completed survey. Respondents were similar to non-respondents with respect to age, gender, race, BMI, education, marital status and perceived general health. Respondents in the intervention group were similar to those in the control group with respect to all but two demographic characteristics – employment status and income. Respondents in the intervention group were more likely to be employed (See table 4). A significantly higher proportion of the control respondents (25%) did not provide their income compared with intervention respondents (8%).

Response rate: The overall response rate was 76% of all eligible participants. The response rate was higher in the control group (84%) compared with the intervention group (69%). In the intervention group, the majority of respondents (88%) reported watching 50% or more of the DVD and three-fourths (75%) of the respondents reported having read some or all parts of the pamphlet. Age was not associated with watching the DVD or reading the pamphlet. In univariate analysis, the average participation rate was

over 90% for age groups 50 – 59 and 60 – 69; in age groups 70-80, the average participation rate dropped to 82% but this difference was not statistically different ($p = 0.27$). Respondents with a college degree were less likely to watch the DVD but this finding was not statistically significant in univariate logistic regression ($p = 0.08$).

D.3 Participation in Colon Cancer Screening Decision

Despite recommendations that providers promote shared decision-making in CRC screening, many respondents stated that their providers had discussed with them (43%) or even recommended (54%) only one screening option. Twenty-one respondents (10%) reported that no physician or health care provider had discussed any of the screening options available. The most commonly recommended screening test was CSPY (90%), followed by FOBT (37%). About two-thirds of all respondents (63%) reported CSPY as their preferred mode for their upcoming CRC screening. Roughly one-third of all respondents reported previously undergoing CSPY, but this information was not independently verified by a chart review. Verification proved to be difficult because some participants were being followed outside of MFA for CRC screening.

Respondents who reported having had a prior screening experience were asked to rate their participation in the decision-making process. Table 5 presents the distribution of responses for questions about the CRC screening decision process. The majority of participants stated that their previous providers played a greater role in the decision about which colon cancer test to have during their last colon cancer screening decision and that their involvement in decision-making was slightly less than what they had wanted. Less than half of the respondents (45%) reported that they were not informed that there were

choices in what they could do for CRC screening. Although physicians frequently discussed reasons to get a colon cancer test, reasons not to get tested were often not discussed. The majority of respondents also reported that their physicians did not ask which test they preferred.

D.4 Knowledge about Colon Cancer

To address specific aim #1, intent-to-treat analyses were conducted to determine whether exposure to the decision aid would increase participants' knowledge about colon cancer and the different screening options available. In the intervention group, respondents had a higher mean knowledge score (80 ± 18) compared with the respondents in the control group (72 ± 15). The difference between two means was statistically significant in univariate analysis ($p = 0.0006$).

Table 6 shows the distribution of responses to select questions on the knowledge test. Generally, respondents performed well on the multiple choice test (See Appendix F.6). Respondents in both study arms correctly answered that regular testing for CRC is recommended at 50, most CRC starts as a polyp in the colon and that a family history increases the risk of CRC (See Appendix F.6). However, respondents in the control group (62%) were significantly more likely to believe that "CTC did not require a bowel preparation" compared with the intervention group (30%). Respondents in both study groups had difficulty answering a question about whether a CSPY would require a follow up if there was an abnormal test result.

The largest difference in percentages correct between the intervention and the control group was observed in two open-ended questions. The majority of respondents

overestimated the risk for colon cancer incidence and mortality in the two open-ended questions. However, the proportion of the respondents that incorrectly estimated the risk of dying from CRC was significantly higher in the control group (59%) compared with the intervention group (27%). The control (68%) group also incorrectly estimated the risk for being diagnosed with CRC compared with the intervention group (36%). Nearly half of the respondents in the control group overestimated the risk at least by three-fold for both mortality (47%) and incidence (46%) of CRC. A greater proportion of women (37%) overestimated the mortality risk for CRC by three-fold or more compared with men (23%) and this finding was statistically significant ($p = 0.03$).

Table 7 shows results from the intent-to-treat (ITT) univariate and multivariate analyses to determine factors associated with knowledge. In univariate analysis, there was significant difference in knowledge by study arm and by income and race. In ITT multivariate analysis, exposure to the decision aid, non-black race, having a college degree and higher income were associated with higher knowledge (Table 7). Respondents who did not provide their income on average scored 8.2 points lower compared with those with income greater than $75,000. In comparison, respondents who earned less than $75,000 on average scored 5.6 points lower compared with those who earned greater than $75,000. College education was a strong predictor of higher knowledge in the univariate analysis and the association was significant even after adjusting for race, income and the intervention. Additionally, the mean difference in knowledge score between the two study groups was greater among respondents without a college education compared to those with a college education.

A separate analysis compared mean knowledge scores between the two study

groups stratified by education status (college education vs. no college education). The intervention had the greatest effect on knowledge among respondents without college education (results not shown in table). Among respondents without a college degree, the intervention group was significantly more likely to score higher on the knowledge test compared with the control group; the intervention respondents on average scored 13 points higher than the control respondents. Among respondents with a college degree, the knowledge test score did not significantly differ between the intervention and the control group; the intervention respondents scored only five points higher than the control respondents.

Per-protocol analysis (PP) was conducted to determine whether actual participation with the decision aid increased participants' knowledge. The PP analysis included all intervention viewers (n=82) and all controls (n=114). Exposure to the decision aid, non-black race, college degree and income remained strong predictors of knowledge in PP analysis. The mean knowledge score for respondents with income less than $75,000 did not differ statistically from those with income greater than $75,000, after adjusting for race, college degree, employment and the intervention. In comparison, respondents who did not provide their income scored significantly less than those with income greater than $75,000. No other significant changes to the regression coefficients were observed in PP multivariate analysis.

D.5 Respondent Characteristics Associated with Choosing CSPY

D.5.a Respondent characteristics. Table 8 shows an overwhelming preference for CSPY in respondents in both the intervention group and the control group. Univariate analyses found no significant differences in screening test preference between the

intervention and control group.

Table 9 compares respondent characteristics by screening preference for CSPY. A significant difference in screening preference was observed by gender, employment status, prior experience with CSPY and physician recommendation in univariate analysis. In multivariate ITT analysis, employment status, prior experiences with CSPY and physician recommendation remained strong predictors of respondents' preferences towards CSPY in the multivariate analysis. Preference towards CSPY was inversely associated with female gender. However, knowledge was not associated with choosing CSPY.

D.5.b Determinants of choosing CSPY. Table 10 shows results from multivariate logistic regression using values to predict the odds of choosing CSPY. A multiple logistic regression was used to develop a model to predict the probability of choosing CSPY using three screening concerns – "to find colon cancer or polyps early", "to avoid a test that requires you to handle your stool" and "to avoid a test where a tube is put into the rectum. According to the multivariate analysis, the odds of choosing CSPY increased with higher ratings of values in "finding colon cancer or polyps early" and "avoiding a test that requires handling of stool". But, the odds of choosing CSPY decreased with higher rating of the value item "avoiding a test where a tube is put into the rectum". In ITT analysis, the final model, which included three value items, correctly classified 74% of the respondents as either having preference for CSPY or not having preference for CSPY. Respondents whom the model predicted would choose CSPY chose CSPY 88% of the time.

D.6 Value Concordance for Choosing CSPY

D.6.a Value concordance using interaction odds ratios. The following value concordance analyses were performed using the ITT and PP analyses. Respondents varied in their opinions about the importance of the value items when thinking about getting tested for colon cancer (See Figure 4). Respondents who stated a preference for CSPY were statistically more likely to highly value the importance of "finding colon cancer or polyps early", "knowing whether or not you have colon cancer", "avoiding handling of stool" but less likely to value the importance of "avoiding a tube is put into the rectum" and "avoiding a test where you have to drink a liquid".

Table 11 shows results from ITT univariate and multivariate comparisons of odds ratios from two study groups with regard to their' preference for CSPY. In general, respondents in the intervention group were more likely to place emphasis on value items that matched test attributes of CSPY. In the intervention group, the odds of choosing CSPY significantly decreased with higher ratings of "avoiding a tube", "avoiding bleeding or a tear" and "avoiding a bowel prep" but the odds increased with higher rating of "knowing whether or not you have colon cancer". In the control group, the odds of choosing CSPY significantly increased with higher ratings of "finding colon cancer or polyps early", "knowing whether or not you have colon cancer" and "avoiding handling of stool" but the odds decreased with higher rating of "avoiding a tube". However, the odds of choosing CSPY was not significantly associated values "avoiding bleeding or a tear" and "avoiding drinking a bowel prep" in the control group. Results from multivariate logistic regression for predicting preference for CSPY showed a nonsignificant effect modification of value ratings by the intervention (See Table 11).

Intervention respondents did not significantly differ from the control respondents in how their values related to choosing CSPY. However, the trend is in the expected direction. For example, respondents in the intervention group who highly rated the importance of "avoiding handling of stool", "avoiding a tube" and "avoiding drinking a bowel prep" had even lower odds of choosing CSPY compared to the control group. Similar findings were noted in the PP analyses but there were no significant associations between the outcome and values "avoiding bleeding or a tear" and "avoiding drinking a bowel prep" in the intervention group.

D.6.b Value concordance using percent match. Both ITT and PP univariate logistic regressions were performed to predict the odds of choosing CSPY for each value endorsed, and value concordance was determined by comparing the predicted result of the model with the screening preference endorsed (See Table 12). Higher value concordance scores were observed in the intervention group, as demonstrated by percent match in Table 12. However, the difference in value concordance between the intervention and the control group was not statistically significant. Figure 4 is a forest plot representing results from the univariate analyses of the direction and strength of association between individual value items and choosing CSPY.

These findings address specific aim #2, which sought to determine whether exposure to the decision aid increases value concordance, i.e. whether participants' choice of screening test match their stated values and preferences. Contrary to the hypothesis, value concordance was not significantly higher in the intervention group compared the control group both in the ITT and PP analyses.

D.7 Value Concordance for Choosing FOBT

The value concordance analysis using choosing FOBT as the outcome was limited due to the small sample size. About one-tenth of respondents reported preference for FOBT. Table 13 shows results from ITT univariate and multivariate analyses comparing the odds ratios from two study groups with regard to their' preference for FOBT. In the control group, the odds of choosing FOBT significantly decreased with higher rating of "avoiding handling of stool" in the univariate analysis. In comparison, the odds of choosing FOBT significantly increased with higher ratings of "avoiding a tube" and "avoiding drinking a bowel prep" in the intervention group. Similar findings were reported in PP analyses, except there was no significant association between "avoiding a bowel prep" and choosing FOBT in the intervention group.

The odds ratios for the interaction terms showed a significant effect modification of value ratings by the intervention. Intervention respondents who highly valued the importance of "avoid handling of stool" and "avoiding a bowel prep" had even greater odds of choosing FOBT compared with the control respondents. The interaction between "avoiding drinking a bowel prep" and the intervention is consistent with the test feature of FOBT. In comparison, the interaction between "avoiding handling of stool" and choosing FOBT is misaligned with the test feature. However, the results are based on ratings from nine respondents, two of whom gave the highest rating of 10 for the value item. Each scored 17 and 44 on the knowledge test (out of a possible 100 points).

E. Discussion

E.1 Summary of Overall Results

This study found support for the hypothesis that the use of a decision aid would increase knowledge about CRC compared to a control group receiving usual care. However, the absolute difference in knowledge between the intervention and control groups is small and not clinically important [151]. According to a systematic review of studies using decision aids, a 10 to 15 percent absolute difference on a 100 point scale is considered a clinically important difference in knowledge [151]. The intervention group was generally more knowledgeable about the testing intervals for CSPY and FOBT, CRC mortality risk and incidence risk of CRC, the fact that CSPY involves sedation and that CSPY requires no follow-up if there is abnormal test result. The control group had fairly high knowledge in the absence of access to the decision aid. This may have been due to the fact that roughly half of all respondents had a college education.

In the subgroup analysis by education, the greatest difference in mean knowledge score between two study groups was observed among respondents without a college education. Among respondents without a college education, we observed a clinically important difference of 13 percent absolute difference in mean knowledge score between two study groups. The decision aid is a promising tool that can be used to communicate complex health-related information, especially for individuals without a college education.

The study also found that value concordance was not significantly higher in the intervention group compared with the control group. However, the intervention group had a pattern of higher value concordance compared with the control group but the

difference was not statistically significant. In the intervention group, higher ratings of "avoiding a tube", "avoiding bleeding or a tear", "avoiding drinking a bowel prep" were associated with lower odds of choosing CSPY. The interaction between the intervention and values was not significant, demonstrating that there was no significant difference between the intervention and the control groups in how the values related to choosing CSPY.

E.2 Implications for the Colorectal Cancer Decision Aid

The study indicated that the decision aid is a promising tool in improving knowledge about CRC, especially among patients without a college education. There are many possible explanations for how the Foundation's Colorectal Cancer Decision Aid (CRCDA) might be helpful in improving patients' knowledge about CRC. First, the decision aid includes patient stories – representing a range of positive and negative testimonies from patients who have already received the screening test. The use of patient stories has been endorsed as one of the twelve quality domains of the International Patient Decision Aids Standards (IPDAS) Collaboration [79]. According to Social Cognitive Theory, listening to personal narratives help patients learn vicariously from experiences of other patients like themselves who have previously engaged in a similar decision-making [152]. Given that decision-making is influenced by how the stories are selected and presented [92], the CRCDA was also carefully crafted to include at least one positive and one negative patient testimony.

Second, the CRCDA was provided in two formats – DVD and pamphlet – to facilitate the way patients obtain information. People have different learning styles. The

best approach is the one that works best for each individual. Equipping patients with the right information in the right format is an important part of the decision-making process. The CRCDA includes a DVD of patients describing their experience with different CRC screening tests and testimonies from prominent physicians and researchers and a pamphlet that provides general evidence-based information in plain language easy to understand for non-health care professionals without any medical background.

Finally, the CRCDA could help overcome health illiteracy and innumeracy. The study did not measure participants' baseline health literacy or numeracy prior to viewing the decision aid. However, the fact that the difference in mean knowledge score between two study arms was greater in respondents without a college degree provides some indication that the CRCDA was possibly helpful in addressing the needs of individuals with deficiencies in health literacy and numeracy. Findings from previous studies also suggest that video-based decision aids can meet these challenges by breaking down complex health information [12, 100, 153, 154]. The level of knowledge and understanding required to make an informed decision in CRC screening is quite high. There are numerous national guidelines and multiple screening strategies, each with varying level of scientific evidence and tradeoffs. Decision aids can overcome many challenges by using plain language, clarifying values, presenting probabilities using graphics and diagrams [155].

E.3 Recommendations for Improving the CRCDA

The CRCDA is one of the quality decision aids currently available to guide CRC screening decisions. Overall, respondents were aware of different ways to test for CRC

including “testing the stool for blood” and “looking inside the colon by putting a tube”. The vast majority of respondents knew that most CRCs start as a polyp in the colon and that risk factors such as age over 50 and a family history of CRC may increase the likelihood of developing the disease. Nonetheless, there were several areas with need for improvement.

Contrary to our expectation, the intervention group was less likely to know that inflammatory bowel disease (IBD) is a risk factor for CRC compared to the control group. IBD is a group of inflammatory conditions of the colon and small intestine. Two major types of IBD are ulcerative colitis and Crohn’s disease. It has been reported that CRC risk begins to be significant eight years after the diagnosis pancolitis (colitis of the entire colon) or 12 to 15 years after the onset of left-sided colitis [143]. Therefore, individuals with longstanding IBDs are recommended to undergo surveillance CSPY and biopsy for potential dysplasia or abnormal cells [143]. For these reasons, individuals with IBD were not eligible for participation in this trial because there is a strong medical evidence to support the use of CSPY.

The CRCDA could do a better job making the connection that ulcerative colitis and Crohn’s disease are types of IBDs. Both study groups did poorly on this question but the intervention group was less likely to correctly answer this question. In the intervention group, the absence of the word “inflammatory bowel disease” under the list of risk factors for CRC probably made it more difficult for intervention respondents to correctly answer this question. In the beginning of the DVD, the moderator defines the target audience for the decision aid as average-risk patients considering being screened for CRC. This information is followed by a bullet-point slide, which list conditions that

increase patients' risk for CRC. The list includes CRC, ulcerative colitis, or Crohn's disease, genetic syndromes that increase the risk of CRC, a parent, brother, sister or child with colon cancer or a previous screening that found potentially precancerous growths. The CRCDA, however, fails to mention that ulcerative colitis and Crohn's are two major types of IBDs known to increase risk for CRC. The word "inflammatory bowel disease" should be added to the bullet-point slide with ulcerative colitis and Crohn's disease in parenthesis.

There are other areas that could be improved as well. The side-by-side comparison of screening tests introduces potential bias towards CSPY and the combination of FOBT and FSIG (See Table 14). Both in the video and the pamphlet, the CRCDA compares the test effectiveness of five screening options (See Section C.4.d). Terminologies used to rank effectiveness were effective, more effective and most effective. According to this scale, FOBT and FSIG were considered effective, CTC more effective and CSPY and a combination of FOBT and FSIG were considered most effective (See Table 14). Further, the pamphlet states that CSPY and a combination of FOBT and FSIG are the best screening modalities known to effectively reduce the chance of death from CRC. However, as discussed in Sections B.1 and B.2, there is no direct evidence from randomized clinical trials demonstrating that use of these two 'most effective' screening strategies significantly reduce CRC-related deaths. There is direct evidence supporting the effectiveness of FOBT alone but evidence is insufficient to support the use of FOBT plus FSIG. The Foundation should consider removing this table from the CRCDA because the table introduces bias with lack of strong evidence from the literature.

The CRCDA is generally informative but lacks technical accuracy and can be misleading at time. Both the DVD and the pamphlet provides explanation that all tests, if tested positive, require a follow-up CSPY unless the patient chooses to undergo CSPY as the initial screening test. While this statement generally holds true there are some exceptions to the rule and the CRCDA should provide clarification on this topic. It should be noted that even when a polyp or a mass is found, it may not be removed during CSPY. First, a complete removal of the polyp or the mass is sometimes not possible for technical reasons. Second, there may be concerns regarding coexisting malignancy, incomplete resection and safety regarding endoscopic treatment of large colonic polyps [156-160]. When the polyps cannot be removed endoscopically, the lesion is often biopsied and the patient is referred for surgical therapy [161]. In cases where the lesion can be removed via the colonoscope, follow-up CSPY is done in three to six months to confirm complete resection.

Finally, the CRCDA could incorporate the video slides with consistent information. Lack of consistency in the presentation of information creates a distraction. Currently, the CRCDA introduces one screening strategy at a time and provides information about how the tests are done, what to expect on the day of the exam or the night before if a bowel preparation is required. Possible complications from procedures are also introduced as necessary. A slide appears towards the end of the presentation to provide a take-home message. The content of the slide varies with each screening option. At the present time, slides are used to provide clarifications or address topics not addressed by the moderator or patient testimonies. For example, the slide for CSPY highlight the use of sedation, test frequency and that ‘little or no pain’ is involved. The

slide for FSIG stress the fact that the procedure “takes less time”, “few risks” and “no sedation or recovery time” are involved, and that it is recommended “once every 5 years”. Lack of consistency in the presentation draws attention to selected information, creating a cognitive bias for patients. It is generally believed that most people learn better when information is presented both verbally and visually. The use of the bulleted slide can help reinforce information presented verbally through the moderator. Providing clear and consistent information could improve the effectiveness of the decision aid while facilitating quality learning for patients.

E.4 Implications for the Decisional Quality Instrument

Using the Decisional Quality Instrument, we were able to measure differences in the values “finding colon cancer early”, “knowing whether or not you have colon cancer”, “avoiding handling of stool”, “avoiding a tube”, “avoiding bleeding or a tear in the colon” and “avoiding drinking a bowel preparation” between respondents who stated preference for CSPY and those without preference for CSPY. In comparison, other value items lacked ability to predict the choice of any particular screening test. Choosing CSPY was not associated with “choosing a test where you have to take a sedative”, “avoiding a test that may be painful” and “choosing a test that doesn’t cost a lot”. There are a number of possible reasons for these findings.

It is possible that the value of “avoiding pain” was not predictive of choosing CSPY due to how information was framed in the CRCDA. The bulleted slide for CSPY stated that ‘sedation is used’ and “little or no pain” is involved. Therefore, individuals who chose to undergo CSPY may not have felt the need to also “avoid pain” and “take a

sedative". The value of "avoiding pain" and "choosing a test where you have to take a sedative" are also closely related concepts; people who value "avoiding pain" are probably more likely to choose a test where they have to "take a sedative"; the correlation is 0.45 between these two items in the current study. It is not entirely clear why these values were not associated with choosing CSPY. Although these values did not significantly differ between individuals who chose CSPY and those who did not, respondents varied in their opinions about "avoiding pain" and "choosing a test where you have to take a sedative". The standard deviations associated with these values indicated some moderate variability among individual responses ("take a sedation", *sd* = ±3.7; "avoid pain", *sd* = ± 2.9).

One possible explanation why "choosing a test that doesn't cost a lot" was a poor predictor of choosing CSPY is that the study population in this study was fully insured and cost consideration may not have been important to them. In our population, about two-thirds of the respondents were reported to be employed. Even in the current economy, the majority of Americans are covered by employment-based insurance [162]. Also of note, more than a quarter of the respondents were eligible for Medicare, whose benefits since 2001 include screening CSPY with no out-of-pocket cost for patients [163].

Further, it is possible that these measures are simply not good predictors for choosing CSPY. First, CRC screening decisions are complicated by patient preferences, scientific certainty, accuracy, benefit and safety and the DQI may not have captured the complexities of the decision. The number of values used in DQI to clarify patient values provides some indication regarding the difficulty of the decision. Previous studies using

DQI have predicted the treatment decision using as little as three to four values [64, 104]. The DQI for CRC uses a total of ten values to capture a determinant of screening decisions. However, it is entirely possible that consideration of even additional values may have influenced the screening decision.

Second, patients may not be as engaged in the CRC decision-making as they are in other decisions, such as those who have participated in studies that examined treatment preferences for early-stage breast cancer and benign prostatic hypertrophy (BPH) [64, 104]. Women facing treatment for early stage breast cancer must decide between undergoing mastectomy alone or lumpectomy combined with radiation. Sepucha found that the decision to undergo mastectomy was predicted by the importance of "keeping the breast" and "avoiding radiation" [64]. Similarly, Barry observed that choosing prostatectomy was predicted by the severity of symptoms, negative ratings of remaining in the symptom state while 'watchful waiting' was predicted by negative ratings of potential post-op impotence [104]. Both treatment decisions involve dichotomous choices. In comparison, CRC screening involves five or more choices, and patients must carefully consider benefits and risks of each screening option. Compared with patients facing treatment decisions for BPH and breast cancer, patients facing CRC screening decisions may not have carefully rated the values. BPH treatment may involve a potential sexual side effect post-operatively while early stage breast cancer treatment involves a loss of a body part. In comparison, CRC decisions are less emotionally charged because there are no irreversible consequences to the decision, unless a complication results. Moreover, the effect of choices on the quality of medical decisions is largely unknown. Some have alluded to the fact that more choices lead to bad decisions [164, 165].

However, a study which offered different numbers of CRC screening options (two vs. five options) concluded that the number of screening options has no effect on test choice and screening interest [94]. To the extent that more choices do not always lead to better health outcome, a great effort has to be made to provide accurate and relevant information to patients.

Third, dichotomizing the outcome may have contributed to poor differentiation of values between patients who chose CSPY and those who did not. In this study, the outcome of interest was participants' choice of CRC screening test. The majority of the respondents stated preference for CSPY (65%), followed by FOBT (12%). The combination of the small sample size and a strong preference for CSPY were reasons for dichotomizing the outcome to compare individuals who chose CSPY to those who did not. By doing so, this may have obscured any associations between values and screening preferences. For example, neither the importance of "avoiding pain" nor "avoiding sedation" was associated with lower odds of choosing CSPY, possibly because some non-CSPY screening methods such as FSIG and CTC are also consistent with those values. Future studies could obtain a larger sample size to allow comparisons of values across the spectrum of screening options.

The practical implication of the survey findings is that the DQI can be used to reveal knowledge deficits and patient preferences. Currently, there are several demonstration sites in the United States that are administering the DQI survey to patients prior to a health maintenance visit. The breast cancer program and the Spine Center at the Dartmouth Health Medical Center and breast cancer centers at the University of California, San Francisco are among the few centers that are using decisional quality

measures along with video-based decision aids to improve value concordance. Information provided by the DQI can help physicians provide a tailored education to address patients' lack of knowledge and understand patients' values to help them choose a concordant test. Further, in order to improve the quality of screening decisions, we need to consistently measure it. As discussed in the background, the current rate of CRC screening is suboptimal. Major contributors to the low screening rate include lack of knowledge among patients about the availability of various screening options, multiple screening alternatives with significant tradeoffs and lack of consensus in current screening guidelines. At the present time, screening decisions are made with little input from patients and are largely influenced by physician bias. In order to improve the quality of CRC screening decisions, a greater effort must be made to understand whether the screening decision reflect values of informed patients.

E.5 Recommendations for the Decisional Quality Instrument

Choosing the appropriate question format is one of the many challenges of developing a quality instrument. The DQI is in large part well thought out and appropriate for measuring patient knowledge. As previously discussed in Section C.5, the DQI is composed largely of multiple-choice questions with a few open-ended questions. Multiple-choice questions generally did not pose significant problems for respondents. However, the knowledge question (3.8b) regarding follow-up CSPY should be examined to verify its technical accuracy.

Asking a question that is not technically accurate not only creates confusion but also make answering difficult for people [166]. The purpose of the question 3.8b is to

understand respondents' knowledge of whether or not a follow-up CSPY is needed if there is an abnormal test result on CSPY. According to the rubric provided by the developer, the answer to the question is "no". As discussed in Section E.3, the CRCDA, although misleading, does address this topic in the decision aid. Due to a myriad of issues surrounding this question, less than half of the intervention respondents correctly answered this question. This seemingly simple question is much more complicated than what appears on the surface. Several clarifications need to be made regarding this question. First, some experts may argue that even with a CSPY, not all polyps are removed (See Section E.3). Second, the "follow up colonoscopy" the question is referring to is not surveillance CSPY, which is a repeat examination typically performed one to five years following the index CSPY to look for regrowths. A follow-up CSPY in the context of the question 3.8b is a diagnostic procedure performed in patients currently with symptoms or previously tested positive for FOBT, FSIG or CTC. Under these circumstances, a CSPY is indicated to confirm a diagnosis of CRC but it is generally not performed on the same day. These symptomatic patients are referred to a gastroenterologist or a colorectal surgeon for further work-up. Based on the findings in this study, this question should be eliminated from the survey.

The use of open-ended questions to assess respondents' knowledge of mortality risk and incidence of CRC should also be further explored. Respondents experienced difficulty answering these open-ended questions. Overall, only about half the respondents correctly answered questions concerning mortality risk and incidence of CRC, although a significantly greater portion of the intervention respondents answered these questions correctly. Open-ended questions are generally used to avoid influencing respondents'

answer, but the downside is that respondents are more likely to skip these items or leave them blank [166]. When answering these open-ended questions, respondents sometimes chose to provide numbers with decimals or a range of numbers to answer this question. The rubric currently does not provide detailed instruction on how to grade these responses. Based on personal communication with the developer, decimals were rounded up and a range of numbers were added and divided by two [167]. The lack of precision with individual scores indicates the need for an alternative method of eliciting responses. The updated version of the DQI currently uses multiple-choice questions to assess patients' knowledge of mortality risk and incidence of CRC. Being able to accurately assess patients' risk perception through these questions is critical to deciding whether informed decision-making took place. As per Health Belief Model, it is possible that overestimating the risk for getting or dying from CRC may increase the likelihood of patients undergoing a screening test [152]. However, the end goal of the CRCDA is to promote shared-decision making, not to get more people to get tested for CRC.

The value rating questions (Q 2.4) were cognitively difficult and time-consuming for patients. The question asked respondents to read items A through J, choose three of ten important items and rank them in the order of importance (See Appendix F.4). Three consecutive lines were provided below the question so respondents can write in the letter associated with the item important to them when thinking about the kind of CRC test to have. Ranking questions are incredibly difficult for respondent to understand and complete correctly [166]. In fact, as much as 15% of respondents left this question blank. Respondents who completed this question answered it in several different ways. Some respondents listed more than one items in the first line but left other lines blank. Other

respondents listed more than one items for each line. One explanation for this respondent behavior is that answer spaces are sized larger than the information requested. Research has shown that the size of the answer boxes are highly influential in how respondents answer the question; a small box is desirable when little information is needed but a larger box is desirable when a lot of information is expected [166]. The size of the lines should be reduced to fit only one letter per line. Currently, the size of the lines can accommodate as many as four or five letters. Alternatively, the instructions might ask respondents to rank the items by placing numbers in front of each item (e.g., #1 for their most important choice, #2 for the second and so on.).

Finally, items "finding colon cancer early" and "knowing whether or not you have colon cancer" were highly correlated. One possible explanation for the high correlation between these values is that respondents could not differentiate between two values. Further, the use of these values is unclear. These values are listed under Section 2.1 to elicit patients' preferences regarding whether or not to get tested for CRC. The value item "knowing whether or not you have colon cancer" implies the importance of diagnosing CRC when a patient is symptomatic, tested positive on FOBT or a suspected mass is seen on X-ray, CT or MRI imaging. On the contrary, the value item "finding colon cancer early" refers to the importance of early detection of polyps prior to the progression to symptomatic CRC. An argument against differentiating between these two values is that all screening tests are used for early detection. To a patient with no medical background, there may be no discernable differences between these values. Both value items appear to have an association with choosing CSPY in univariate logistic analysis. But, the lack of association between these highly correlated values and outcome in multivariate logistic

regression provides justification to combine them into one value item that patients can easily understand. The value items should be meaningfully regrouped as the goal of "choosing a test that can find colon cancer or polyps early", referring to both the importance of early detection of polyps and diagnosing CRC. Further, the new value item "choosing a test that can find colon cancer or polyps early" should become part of what is currently the DQI Section 2.2, which measures important considerations in choosing a screening test.

E.6 Strengths and limitations of the study

E.6.a *Strengths.* The major strength of this study is the use of a randomized controlled trial for evaluating the effectiveness of a decision aid. The study design allowed direct comparison of knowledge about CRC between a group of patients who had an opportunity to read the pamphlet and to watch the DVD with that of a control group of patients from the same practice. There also was effective recruitment into the study; 280 out of 307 (91%) volunteers who were approached consented to participate in the study. The recruitment efficacy further yielded a moderately high overall return rate of the surveys. Further, almost everyone in the intervention group who returned the survey reported either watching the DVD or reading the pamphlet.

Another strength of this study was the extent to which it examined the effectiveness of the intervention in a real life setting and assessed patients' compliance with the decision aid when it is given to them. The findings of high compliance with reading and viewing the CRCDA among the respondents provide valuable information about expected compliance rates for future studies and intervention implementation. The

majority of respondents (88%) reported watching the DVD, which represents about 61% viewer rate among the entire intervention group. This is a conservative estimate that assumes that all individuals who did not return the survey did not watch the DVD.

The study is the first to assess the quality of CRC screening decisions in a clinical setting. The study had sufficient power to be able to detect differences in values between individuals with preference for CSPY and those without preference for CSPY. Findings indicated that highly rating the importance of 'avoiding a tube', avoiding bleeding or a tear' and 'avoiding drinking a bowel prep' were all associated with the lower odds of choosing CSPY.

A final strength of this study is the use of a systematic approach to documenting patients' knowledge and values. The study assessed knowledge and values about CRC using a set of survey items that both clinical experts and patients agreed were important to a quality screening decision. Previous studies have used measures that relied on patient perceptions of 'feeling informed' and 'satisfaction with decision' as surrogates for a good decision. The present study, based upon knowledge gained from the use of the decision aid, elicited information from patients regarding their personal wishes and values regarding screening and measured the concordance between stated values and choices for screening.

E.6.b *Limitations.*

This study had a number of methodological limitations. First, the subjects in this study were recruited from a single academic medical center in downtown Washington, DC. Participants from the trial came from the District of Columbia, Virginia and Maryland where there are high rates of CSPY use [54]. Respondents reported an

overwhelming preference for CSPY, regardless of the study group. Future studies should be conducted in an area where there is a lack of strong preference for CSPY. Another limitation is that the study population was predominantly employed, well-educated and highly insured. Therefore, results are not generalizable to less educated population without a college degree. Future studies could address these limitations by conducting the study in a clinical setting with less educated patients. The difference in mean test score between the intervention and the control group may be greater in a less educated population, given the finding that the difference in knowledge was greater between study arms in respondents without a college degree. The study is not generalizable to nonclinical settings because it is geared towards patients who are considering whether to get tested for CRC.

Second, the response rate in the intervention group was much lower than the control group. Participants who did not return the completed survey are probably less likely to have viewed or read the decision aid materials. Among intervention respondents, almost everyone reported watching the DVD, reading the pamphlet or both, but this only represents about two-thirds of the total participants. To get a better sense of the efficacy of the CRCDA, future studies should have participants watch the DVD and read the pamphlet in the clinic prior to being sent home with the DQI. Moreover, the knowledge test was self-administered after the educational intervention but not before. Consequently, it is not possible to assess the extent to which the decision aid improved the knowledge score. A randomized controlled design generally ensures that the intervention and control groups are similar in all respects, but without baseline information on knowledge scores, it is impossible to know whether the study arms were truly balanced on baseline

knowledge. Information about pre-test knowledge would also provide additional data on whether respondent knowledge improved significantly after viewing and reading the decision aid. Further, comparing pre and post-test knowledge could help point out areas for improvement for the decision aid.

Finally, administering the DQI to patients after a visit with their provider may have introduced a potential physician bias toward CSPY. The majority of respondents reported receiving a physician recommendation to undergo CSPY and also stated their own preference for CSPY. In multivariate analysis, a physician recommendation was one of the strongest predictors for choosing CSPY. To accurately measure patient preferences for CRC screening, the DQI should be administered prior to a visit with a health care provider. In our study, about two-thirds of respondents stated preference for CSPY. A 2008 article assessed patients' CRC screening preference after reviewing a decision aid but without a visit with a provider and found that less than half of participants who viewed the five-option decision aid reported preference for CSPY [94]. Using the DQI to measure patient values and preferences prior to a visit with a doctor may allow for a more accurate assessment of patient values while preventing physician bias from dictating patient preferences.

E.6 Recommendations for future research

Future studies should evaluate the relationship between the values and knowledge. The current study was not powered to examine the association between knowledge and values. Findings from this study generally support that values are associated with the choice of screening test. However, there is lack of data about how

increased knowledge impacts concordance between patients' choice and their values. Evidence demonstrating the link between knowledge and values would provide insights about areas of focus for the decision aid. For example, this study found that the intervention group had a pattern of having a higher value concordance based on value of "choosing a test that does not need to be done ever year" compared to the control group. If new research findings suggest that patients who know that CSPY is performed every ten years are more likely to value "choosing a test that does not need to be done ever year", then the decision aid may be more careful in presenting information about testing intervals. Further studies in this area are warranted to examine the association between knowledge and values.

Measuring numeracy and health literacy prior to administering the DQI could provide valuable information about whether the decision aid has a differential effect by literacy and numeracy level. Currently, there are several validated instruments that can be used to assess for patients' health literacy and numeracy [168-171]. Health illiteracy and innumeracy have been associated with poor health outcomes [70, 71]. But, further studies should explore the association between health literacy, numeracy and the quality of CRC screening decisions and whether use of decision aids can improve the quality of CRC decision even in patients with poor health literacy and numeracy.

E.7 Conclusion

In conclusion, this study found that the CRCDA significantly improves patients' knowledge about CRC, especially among patients without a college education. Even in a highly educated sample of patients, however, the use of the CRCDA resulted in higher

knowledge scores. The study also found that the intervention group had a pattern of having values consistent with their choice of screening test but the study was not powered to detect this difference. The CRCDA is a promising tool that can be used to supplement physician counseling to educate patients about CRC and various screening tests.

The DQI for CRC screening decisions can help identify patients with knowledge deficits and reveal screening preferences before a decision is made regarding which test to choose. Future studies could look at whether the DQI can help clarify values. This study employed the DQI after each patient had spoken with their physician about CRC screening and had made a choice. The decision aid may have a greater effect on clarifying values if the instrument were used prior to the physician visit. Together, the CRCDA and the DQI are powerful tools in improving and assessing the quality of screening decisions.

The development of the DQI is still in the early stages. Previous measures that have been used to assess the quality of decisions do not measure decisional quality because they rely on patients' perception of how informed and satisfied they are. Even though this study identified some areas in which more work is needed in further refinement and validation of the DQI, the systematic approach to documenting patients' knowledge and values it brings in its present state will help improve the way decisions are made in a clinical setting.

No previous study has examined the quality of CRC screening decisions. This study represents the first effort to characterize the association between patient values and the screening choice. The study may contribute to efforts to measure quality of CRC screenings in a clinical setting. Because patients' values were measured after their

discussion with a physician, there was a strong preference towards CSPY perhaps for a number of reasons. Future studies should measure values prior to the physician visit. Further, future studies should investigate the interaction between knowledge and values and their effect on the screening choice. Further work is also needed to validate the DQI instrument and increase the effectiveness of the CRCDA in improving knowledge in patients without a college education.

Appendix F.1 Inclusion and Exclusion Criteria (1 of 1)

Subject ID: _____ Date: _____

Inclusion Criteria:

Patients between 50 – 80 years of age with an average risk of colorectal cancer

Yes ☐ No ☐

Exclusion Criteria:

Any of the following findings will exclude a patient from consideration for the study.

Positive guaiac-based test of stool within 6 months before referral	Yes ☐ No ☐
Iron-deficiency anemia within previous 6 months	Yes ☐ No ☐
Rectal bleeding or hematochezia within previous 12 months	Yes ☐ No ☐
Unintentional weight loss of more than 10 lb within previous 12 months	Yes ☐ No ☐
Optical colonoscopy within previous 5 years	Yes ☐ No ☐
Barium enema within previous 5 years	Yes ☐ No ☐
CT Colonography within previous 5 years	Yes ☐ No ☐
Family history of colon cancer in first-degree relative before the age of 60 years	Yes ☐ No ☐
History of adenomatous polyps, colorectal cancer, or inflammatory bowel disease	Yes ☐ No ☐
History of familial adenomatous polyposis or hereditary nonpolyposis cancer syndromes.	Yes ☐ No ☐
Pregnancy	Yes ☐ No ☐

Appendix F.2 Data Collection Form #1

Subject ID: _____ Date: _____

AGE: _____

SEX: Male ☐ Female ☐

Height: _____ inches Weight: _____ lbs BMI: _____

Race?
☐ American Indian/Alaska Native
☐ Asian
☐ Black/African American
☐ Native Hawaiian/Other Pacific Islander
☐ White

Education:
☐ No high school diploma
☐ High school only
☐ Some college, no degree
☐ College degree
☐ Some graduate education

Income:
☐ < $20,000
☐ $20,000 – 49,999
☐ $50,000 – 74,999
☐ $75,000 – 99,999
☐ $100,000 and above

Occupational status:
☐ Employed
☐ Unemployed
☐ Homemaker
☐ Student
☐ Retired
☐ Disabled
☐ Other:
Please specify _____

Marital Status:
☐ Married
☐ Living as married
☐ Divorced
☐ Widowed
☐ Separated
☐ Single, never been married

Have you smoked at least 100 cigarettes in your entire life? Yes ☐ No ☐

How often do you now smoke cigarettes?
☐ Every day
☐ Some days
☐ Not at all

Appendix F.2 Collection Form #1 (2 out of 4)

On the average, how many cigarettes do you now smoke a day? _____

How often do you have a drink containing alcohol?

☐ Never
☐ Monthly or less
☐ 2-4 times a month
☐ 4 or more times a week

How many drinks do you have on a typical day when you drink?

☐ 1-2
☐ 3-4
☐ 5-6
☐ 7-9
☐ 10 or more

Family history of colorectal cancer? Yes ☐ No ☐

If "Yes", your relationship to the person and age at diagnosis

_____

In general, would you say your health is…

☐ Excellent
☐ Very good
☐ Good
☐ Fair
☐ Poor

Have you ever looked for information about health or medical topics from any source?

☐ Yes
☐ No

The most recent time you looked for information about health or medical topics, where did you go first?

☐ Books
☐ Brochures
☐ Cancer organization
☐ Family
☐ Friend/co-worker
☐ Internet
☐ Library
☐ Magazines
☐ Newspapers
☐ Telephone Information Number
☐ Complementary, alternative or unconventional practitioner
☐ Other → *Please specify below:*

_____
_____

Appendix F.2 Data Collection Form #1 (3 out of 4)

Subject ID: _____ Date: _____

Did you look or go anywhere else?

- ☐ No, nowhere else
- ☐ Books
- ☐ Brochures
- ☐ Cancer organization
- ☐ Family
- ☐ Friend/co-worker
- ☐ Internet
- ☐ Library
- ☐ Magazines
- ☐ Newspapers
- ☐ Telephone Information Number
- ☐ Complementary, alternative or unconventional practitioner
- ☐ Other → *Please specify below:*

_____

_____

The most recent time you looked for information about health or medical topics, who was it for?

- ☐ Myself
- ☐ Someone else
- ☐ Both myself and someone else

Overall, how confident are you that you could get health-related advice or information if you needed it?

- ☐ Completely confident
- ☐ Very confident
- ☐ Somewhat confident
- ☐ A little confident
- ☐ Not confident at all

Do you ever go on-line to access the Internet or World Wide Web, or to send and receive e-mails? Yes ☐ No ☐

Where do you go to use the Internet?

- ☐ Home
- ☐ Work
- ☐ School
- ☐ Public Library
- ☐ Community Center
- ☐ Someone else's house
- ☐ Some other place

Appendix F.2 Data Collection Form #1 (4 out of 4)

Subject ID: _____ Date: _____

Do you ever go on-line to access the Internet or World Wide Web, or to send and receive e-mails? Yes ☐ No ☐

Below are some ways people use the Internet. Some people have done these things, but other people have not. Please tell us whether or not you have done each of these things while using the Internet in the past 12 months.

Bought medicine or vitamins online	Yes ☐	No ☐
Participated in an on-line support group for people with a similar health or medical issue	Yes ☐	No ☐
Used e-mail or the Internet to communicate with a doctor or a doctor's office	Yes ☐	No ☐
Used a website to help you with your diet, weight, or physical activity	Yes ☐	No ☐
Looked for a healthcare provider	Yes ☐	No ☐
Downloaded to a portable device, such as an iPod, cell phone, or PDA	Yes ☐	No ☐
Visited a "social networking" site, such as myspace or Second Life	Yes ☐	No ☐
Wrote in an on-line diary or blog	Yes ☐	No ☐
Kept track of personal health information, such as care received, test results, or upcoming medical appointments	Yes ☐	No ☐

Appendix F.3 Data Collection Form #2

Subject ID: _____ Date: _____

1. Were you provided with a decision aid packet, which consists of a 30-minute video and a written pamphlet?
   ___ Yes
   ___ No (Please go to Question #2 below)

If "Yes", please answer following questions:

1a. Please select the statement below that best describes how you watched the video:

___ I watched the entire video

___ I watched more than half the video but not all of it

___ I watched less than half the video

___ I did not watch the video

Reason for not watching the video: _____

1b. Please select the statement that best describes what you read of the pamphlet:

___ I read the pamphlet in detail

___ I read some parts of the pamphlet

___ I briefly scanned the contents of the pamphlet

___ I did not read the pamphlet

Reason for not reading the pamphlet: _____

2. Please select your preferred method colon cancer screening:

___ Fecal Occult Blood Test

___ Flexible Sigmoidoscopy

___ A Combination of Fecal Occult Blood Test and Flexible Sigmoidoscopy

___ Colonoscopy

___ Double-Contrast Barium Enema

___ CT Colonography

___ No screening

3. In your own words, please describe the reason(s) for your choice of colon cancer screening test.

_____
_____
_____
_____

Appendix F.4 Decisional Quality Instrument

Colon Cancer Testing:
A survey about your experiences making decisions

SURVEY INSTRUCTIONS

- The survey contains questions about your experiences selecting colon cancer tests and your understanding of different screening tests for colon cancer.
- Please check the box ☑ to answer each item.
- Your participation in this study is voluntary. If you come across a question you would rather not answer, feel free to skip it and go on to the next question.
- Your answers are confidential. No information will be presented or published in any way that would permit identification of any individual. Your name and answers will not be shared with anyone other than the researchers.
- When you are done, please return the completed survey in the stamped envelope provided.
- Thank you, we really appreciate your help

SECTION 1: TALKING WITH DOCTORS ABOUT COLON CANCER TESTING

Please answer these questions about what happened when you talked with doctors, nurses and other health care professionals about the different choices available for colon cancer testing.

1.1 Did your doctors explain that there were choices in what you could do for colon cancer testing?

☐ Yes
☐ No

1.2 For each of the following colon cancer tests, please mark whether or not any doctor or health professional ever **talked to you** about it.

a.	Stool Blood Test	☐ Yes	☐ No	☐ Not sure
b.	Colonoscopy	☐ Yes	☐ No	☐ Not sure
c.	Sigmoidoscopy	☐ Yes	☐ No	☐ Not sure
d.	CT Scan	☐ Yes	☐ No	☐ Not sure
e.	Other (write in: _____)			

1.3. For each of the following colon cancer tests, please mark whether or not any doctor or health professional ever **recommended** it to you.

a.	Stool Blood Test	☐ Yes	☐ No	☐ Not sure
b.	Colonoscopy	☐ Yes	☐ No	☐ Not sure
c.	Sigmoidoscopy	☐ Yes	☐ No	☐ Not sure
d.	CT Scan	☐ Yes	☐ No	☐ Not sure
e.	Other (write in: _____)			

1.4 How much did your health care providers talk about the reasons to be tested for colon cancer?

☐ A lot
☐ Some
☐ A little
☐ Not at all

SECTION 1: TALKING WITH DOCTORS ABOUT COLON CANCER TESTING

Please answer these questions about what happened when you talked with doctors, nurses and other health care professionals about the different choices available for colon cancer testing.

1.1 Did your doctors explain that there were choices in what you could do for colon cancer testing?

☐ Yes
☐ No

1.2 For each of the following colon cancer tests, please mark whether or not any doctor or health professional ever **talked to you** about it.

a.	Stool Blood Test	☐ Yes	☐ No	☐ Not sure
b.	Colonoscopy	☐ Yes	☐ No	☐ Not sure
c.	Sigmoidoscopy	☐ Yes	☐ No	☐ Not sure
d.	CT Scan	☐ Yes	☐ No	☐ Not sure
e.	Other (write in: _____)			

1.4. For each of the following colon cancer tests, please mark whether or not any doctor or health professional ever **recommended** it to you.

a.	Stool Blood Test	☐ Yes	☐ No	☐ Not sure
b.	Colonoscopy	☐ Yes	☐ No	☐ Not sure
c.	Sigmoidoscopy	☐ Yes	☐ No	☐ Not sure
d.	CT Scan	☐ Yes	☐ No	☐ Not sure
e.	Other (write in: _____)			

1.4 How much did your health care providers talk about the reasons to be tested for colon cancer?

☐ A lot
☐ Some
☐ A little
☐ Not at all

1.5 How much did your health care providers talk about the reasons not to be tested for colon cancer?

- A lot
- Some
- A little
- Not at all

1.6 Did any of your health care providers ask you which type of colon cancer test you wanted?

- ☐ Yes
- ☐ No

1.7. For each of the following colon cancer tests, please mark whether or not you **have had the test**.

a.	Stool Blood Test	☐ Yes	☐ No	☐ Not sure
b.	Colonoscopy	☐ Yes	☐ No	☐ Not sure
c.	Sigmoidoscopy	☐ Yes	☐ No	☐ Not sure
d.	CT Scan	☐ Yes	☐ No	☐ Not sure
e.	Other (write in: _____)			

1.8. In what month and year was your most recent colon cancer test?

_____MONTH _____ YEAR

1.9. Think only about your most recent colon cancer test. Who made the decision about which colon cancer test you had? Please put an "X" in the box that is closest to how the decision was made.

Totally you					Both you and your doctor equally					Totally your doctor
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

1.10. How much were you involved in making the decision about your most recent colon cancer test?

Much less than you wanted					About as much as you wanted					Much more than you wanted
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

SECTION 2: WHAT MATTERS MOST TO YOU

People consider many things when thinking about getting tested for colon cancer. We would like to know what is important to you. Please rate each of the items below using any number from 0 to 10, where 0 is not at all important, 5 is somewhat important, and 10 is extremely important.

2.1. When you think about whether or not you want to have a test for colon cancer, how important is it to you …

		Not at all important to me					Somewhat important to me					Extremely important to me
a.	…to try to find colon cancer or polyps early?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐
b.	…to know whether or not you have colon cancer?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐

2.2. When you think about which kind of colon cancer test to have, how important is it to you …

		Not at all important to me					Somewhat important to me					Extremely important to me
a.	…to choose a test that does not need to be done every year?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐
b.	…to choose a test where you take medicine before the test that makes you sleepy?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐
c.	... to choose a test that doesn't cost you a lot of money	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐

2.3. When people think about which kind of colon cancer test to have, sometimes there are things they specifically want to **avoid**. What number would you use to rate how important it is to you …

		Not at all important to me					Somewhat important to me				Extremely important to me
a.	…to **avoid** a test that requires you to handle your stool?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐
b.	…to **avoid** a test that may be painful?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐
c.	…to **avoid** a test where a tube is put into your rectum to look at the colon?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐
d.	…to **avoid** a test that can cause bleeding or a tear in the colon?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐
e.	…to **avoid** a test where you have to drink a liquid before the test to clean out the colon?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐

2.4. Of the items you just rated, which are the three most important to you when you think about which kind of colon cancer test to have? Please write in the letter of your answer on the lines below.

Most important to me: _____

Second most important: _____

Third most important: _____

A. Trying to find colon cancer or polyps early
B. Knowing whether you have colon cancer
C. Having a test that does not need to be done every year
D. Having a test where you take medicine before the test that makes you sleepy
E. Having a test that doesn't cost you a lot of money
F. Avoiding a test where you have to handle your stool
G. Avoiding a test that may be painful
H. Avoiding a test where a tube is put into your rectum
I. Avoiding a test that can cause bleeding or a tear in the colon
J. Avoiding a test where you have to clean out your colon beforehand

SECTION 3: FACTS ABOUT COLON CANCER TESTS

These questions ask about your understanding of colon cancer tests. The correct answers are based on medical research and practice. Please do your best to answer each question, even if you did not have the test discussed in the question.

3.1. For each of the following mark whether it is a way to test for colon cancer.

a.	Testing a urine sample	☐ Yes	☐ No
b.	Testing the stool for blood	☐ Yes	☐ No
c.	Looking inside the colon by putting a tube in the rectum	☐ Yes	☐ No
d.	Testing blood taken from the arm	☐ Yes	☐ No

3.2. At what age do doctors usually recommend people start getting regular tests for colon cancer?

☐ 30
☐ 40
☐ 50
☐ 60

3.3. How do most colon cancers start?

☐ As a tear in the colon
☐ As a polyp in the colon
☐ As a result of constipation
☐ As a hemorrhoid

3.4. For each of the following, mark whether or not it can increase the chance of a person getting colon cancer.

a.	Being over age 50	☐ Yes	☐ No
b.	Having a history of inflammatory bowel disease	☐ Yes	☐ No
c.	Having heart disease	☐ Yes	☐ No
d.	Having a family history of colon cancer	☐ Yes	☐ No

3.5. You may not know the exact number, but please take your best guess. Out of every 100 people, about how many will **get** colon cancer some time in their lives?

_____ Write in number of people

3.6. Before some tests for colon cancer, people may be required to clean out their colon by drinking a lot of liquid that makes them move their bowels a lot. For each of the following colon cancer tests, mark whether or not it usually requires people to clean out their colon before the test.

a.	Stool Blood Test	☐ Yes	☐ No
b.	Colonoscopy	☐ Yes	☐ No
c.	Sigmoidoscopy	☐ Yes	☐ No
d.	CT scan	☐ Yes	☐ No

3.7. For each of the following colon cancer tests, mark whether or not it usually requires people to take medicine that makes them sleepy during the test.

a.	Stool Blood Test	☐ Yes	☐ No
b.	Colonoscopy	☐ Yes	☐ No
c.	Sigmoidoscopy	☐ Yes	☐ No
d.	CT scan	☐ Yes	☐ No

3.8. For each of the following colon cancer tests, if there is an abnormal test result, mark whether or not a follow-up colonoscopy is needed.

a.	Stool Blood Test	☐ Yes	☐ No
b.	Colonoscopy	☐ Yes	☐ No
c.	Sigmoidoscopy	☐ Yes	☐ No
d.	CT scan	☐ Yes	☐ No

3.9. Does having a colon cancer test result that is **not** normal always mean that a person has colon cancer?

☐ Yes
☐ No

3.10. How often do serious problems, such as serious bleeding or a tear in the colon, happen as a result of a colonscopy?

- ☐ Usually
- ☐ Sometimes
- ☐ Rarely
- ☐ Never

3.11. For a person with an average risk for colon cancer, which test do doctors recommend be done **every year**?

- ☐ Stool Blood Test
- ☐ Colonoscopy
- ☐ Sigmoidoscopy
- ☐ CT Scan

3.12. For a person with an average risk for colon cancer, which test do doctors recommend be done **every 10 years**?

- ☐ Stool Blood Test
- ☐ Colonoscopy
- ☐ Sigmoidoscopy
- ☐ CT Scan

3.13. How does regular testing for colon cancer change the chances that a person will die from colon cancer?

- ☐ Increases the chance of dying from colon cancer
- ☐ Decreases the chance of dying from colon cancer
- ☐ Does not change the chance of dying from colon cancer

3.14. Which colon cancer test is least likely to **miss** a cancer?

- ☐ Stool Blood Test
- ☐ Colonoscopy
- ☐ Sigmoidoscopy
- ☐ CT Scan

3.15. If the results of a colon cancer test are normal, is it possible that a person could still have colon cancer?

- ☐ Yes
- ☐ No

3.16. You may not know the exact number, but please take your best guess. Out of every 100 people, about how many will **die** of colon cancer?

_____ Write in number of people

Appendix F.5 CRC DQI Scoring Instruction

Colorectal Cancer Screening Decision Quality Instrument
Summary and Scoring Instructions

Development

The Colorectal Cancer Screening Decision Quality Instrument (CRC-DQI) measures the quality of decisions for men who have been screened for colorectal cancer. The definition of decision quality is the extent to which treatments received reflect the considered preferences of informed patients. (Sepucha 2004) The instrument has three types of items that are scored separately. (1) A set of knowledge items that are summed to create a knowledge score, (2) a set of items that assess the level of involvement in patients during the interaction with providers, and (3) a set of goals and concerns that are used to examine the level of concordance between patients' preferences and the treatments that are received. Additional data that needs to be collected (either from patient self report or medical record) includes the treatment received. The definition and approach is based on the framework outlined by Sepucha and colleagues (Sepucha 2004).

The development process was similar to that for breast cancer and symptom driven conditions and has been described in detail (see Sepucha et al 2006; Sepucha et al 2008; Lee et al 2010). A brief summary of the process for CRC-DQI is as follows. The key facts and goals were identified after a review of the clinical literature and patient focus groups. The content was then evaluated by a convenience sample of men and women (n=27) who had recently made a decision about testing and a multidisciplinary group of providers (n=19). The content was revised based on results until it was considered important, accurate and complete. Experts in survey research then drafted multiple choice and open-ended items as well as scaling tasks to cover the content in these areas. The items were cognitively tested with 6 people who were at average risk for developing colorectal cancer. Patients with colon cancer were excluded. Additional edits were made to increase comprehension and acceptability based on the results of cognitive testing.

The items about the interaction and level of involvement were based on the key decision process areas identified by IPDAS: (1) recognize a decision (discussion of more than one option) (2) discussion of the pros (3) discussion of the cons and (4) discussion of patients' preferences (Elwyn et al 2006). These involvement items were also drafted by experts in survey research and were cognitively tested. Early versions were used in the DECISIONS study (Zikmund Fisher et al, 2010). They have also been used in a recent Medicare study with heart disease, prostate and breast cancer patients.

The rigorous and lengthy development process involved significant input and feedback from patients as well as providers and was designed to ensure content and clinical validity.

Timing:

The DQI research version is designed to be administered after a decision has been made. Modifications are required (e.g. to instructions and tenses of items) if it is to be used before a decision has been made.

The short version is worded to be used before a visit with a health care provider can be used before a decision is made (during the deliberation process). This version includes only the decision specific knowledge items and goals and concerns. The involvement items need to be administered after a provider consult.

Scoring:

1. Knowledge (items 3.1-3.16): a total score is calculated as the total number correct divided by the total number of items to yield scores from 0-100. Each correct item gets one point. Items with multiple parts split 1 point even among the options (e.g. for 3.1 respondents get 0.25 for each correct response from a-d). Missing items are imputed with 1/k where k is the number of possible responses. Surveys where more than half of the knowledge items are missing do not receive a total score. The correct answer for each item is indicated by an "X":

3.1. For each of the following, mark whether it is a way to test for colon cancer.

a.	Testing a urine sample……..	☐ Yes	X No
b.	Testing the stool for blood……..	X Yes	☐ No
c.	Looking inside the colon by putting a tube in the rectum……..……..……..	X Yes	☐ No
d.	Testing blood taken from the arm…..……...	☐ Yes	X No

3.2. At what age do doctors usually recommend people start getting regular tests for colon cancer?

☐ 30
☐ 40
X 50
☐ 60

3.3. How do most colon cancers start?

☐ As a tear in the colon
X As a polyp in the colon
☐ As a result of constipation
☐ As a hemorrhoid

3.4. For each of the following, mark whether or not it can increase the chance of a person getting colon cancer.

a.	Being over age 50……..……...	X Yes	☐ No
b.	Having a history of inflammatory bowel disease ……	X Yes	☐ No
c.	Having heart disease…..……..……..	☐ Yes	X No
d.	Having a family history of colon cancer..…….....	X Yes	☐ No

3.5. Out of every 100 people, about how many will **get** colon cancer some time in their lives?

☐ 2
X 6
☐ 14
☐ 24
☐ 43

3.6. Before some tests for colon cancer, people may be required to clean out their colon by drinking a lot of liquid that makes them move their bowels a lot. For each of the following colon cancer tests, mark whether or not it usually requires people to clean out their colon before the test.

a.	Stool blood test…..……..……...	☐ Yes	X No
b.	Colonoscopy…….……	X Yes	☐ No
c.	Sigmoidoscopy…….……..…….	X Yes	☐ No
d.	CT scan……...……....	X Yes	☐ No

3.7. For each of the following colon cancer tests, mark whether or not it usually requires people to take medicine that makes them sleepy during the test.

a.	Stool blood test…….……...	☐ Yes	X No
b.	Colonoscopy…….……	X Yes	☐ No
c.	Sigmoidoscopy…….……..…….	X Yes	☐ No
d.	CT scan……...…….....	☐ Yes	X No

3.8. For each of the following colon cancer tests, if there is an abnormal test result, mark whether or not a follow-up colonoscopy is needed.

a.	Stool blood test…….……...	X Yes	☐ No
b.	Colonoscopy…….……	☐ Yes	X No
c.	Sigmoidoscopy…….……..…….	X Yes	☐ No
d.	CT scan……...…….....	X Yes	☐ No

3.9. Does having a colon cancer test result that is **not** normal always mean that a person has colon cancer?

☐ Yes
X No

3.10. How often do serious problems, such as serious bleeding or a tear in the colon, happen as a result of a colonscopy?

☐ Usually
☐ Sometimes
X Rarely
☐ Never

3.11. For a person with an average risk for colon cancer, which test do doctors recommend be done **every year**?

X Stool Blood Test
☐ Colonoscopy
☐ Sigmoidoscopy
☐ CT Scan

3.12. For a person with an average risk for colon cancer, which test do doctors recommend be done **every 10 years**?

☐ Stool Blood Test
X Colonoscopy
☐ Sigmoidoscopy
☐ CT Scan

3.13. How does regular testing for colon cancer change the chances that a person will die from colon cancer?

☐ Increases the chance of dying from colon cancer
X Decreases the chance of dying from colon cancer
☐ Does not change the chance of dying from colon cancer

3.14. Which colon cancer test is least likely to **miss** a cancer?

☐ Stool Blood Test
X Colonoscopy
☐ Sigmoidoscopy
☐ CT Scan

3.15. If the results of a colon cancer test are normal, is it possible that a person could still have colon cancer?

X Yes
☐ No

3.16. Out of every 100 people, about how many will **die** of colon cancer? Please mark the number that you think is closest to the correct answer.

X 3
☐ 8
☐ 15
☐ 24
☐ 30

Effect size on knowledge: we recommend citing Cochrane systematic review (O'Connor 2007) with ~10-15% absolute difference on a 100 point scale as clinically important difference in knowledge.

2. Involvement (items 1.1-1.10): for now we recommend reporting on these items separately. We are currently conducting a validation study of a summary score.

Two items (1.9 based on Control Preferences Scale and 1.10 based on key criteria from the IPDAS decision process) are included to be reported on separately, if desired. We have found that these have problems with validity, as patients'

descriptions of how the decision was made often do not reflect their responses. Most often, patients follow the doctor's recommendation without meaningful involvement yet indicate that the decision was shared.

3. Concordance score (items 2.1-2.10): This approach follows that used by Barry et al (1995) to examine the extent to which patients' goals are associated with treatments. For CRC, we developed a model of Colonoscopy versus other testing methods (it is possible that others might be interested in FOBT versus other methods, or a different dependent variable). To the extent that there is solid clinical evidence that the approach to screening should vary with selected patient characteristics (age, education, personal risk factors) then those can be included in the model. For our model, we did not include any patient characteristics. First we examined each of the goals in univariate analyses, using t-tests for continuous variables and in multivariable analysis using a logistic regression model with treatment (colonoscopy vs. other methods) as the dependent variable. We use the regression model to determine the model predicted probability of colonoscopy for each patient. Patients with a predicted probability >0.5 and who had colonoscopy and those with a predicted probability ≤0.5 and who did not have colonoscopy would be classified as having tests that match their goals. This yields a summary concordance score that indicated the percentage of people whose decisions "matched" their goals [172].

Citations:

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Lee C, Barry M, Cosenza C, Dominik R, Mulley A, O'Connor A and Sepucha K. Development of instruments to measure the quality of breast cancer treatment decisions. *Health Expectations* 2010; 13(3): 258-72.

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Sepucha K, Ozanne E, Silvia K, Partridge A, Mulley A. An approach to measuring the quality of breast cancer decisions. *Patient Education and Counseling* 2007; 65 (2): 261-269.

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Zikmund Fisher B, Couper M, Singer E, Ubel P, Ziniel S, Fowler FJ, Levin C, Fagerlin A. How Patients Make Nine Types of Common Medical Decisions: Reports from the DECISIONS Survey. *Medical Decision Making* 2010; 30 (5 Suppl): 20S-34S.

Appendix F.6 Distribution of Responses to DQI

Item #	Control, %	Intervention, %	Total, %
1. For each of the following, mark whether it is a way to test for colon cancer			
a. Testing a urine sample			
Yes	9.6	6.5	8.2
No*	**85.1**	**82.8**	**84.1**
Missing	5.3	10.8	7.7
b. Testing the stool for blood			
Yes*	**89.5**	**88.2**	**88.9**
No	8.8	6.5	7.7
Missing	1.8	5.4	3.4
c. Looking inside the colon by putting a tube in the rectum			
Yes*	**93**	**92.5**	**92.8**
No	6.1	4.3	5.3
Missing	0.9	3.2	1.9
d. Testing blood taken from the arm			
Yes	11.4	8.6	10.1
No*	**82.5**	**81.7**	**82.1**
Missing	6.1	9.7	7.7
2. At what age do doctors usually recommend people start getting regular tests for colon cancer?			
30	2.6	0	1.4
40	6.1	5.4	5.8
50*	**86.8**	**92.5**	**89.4**
60	3.5	2.2	2.9
Missing	0.9	0	0.5
3. How do most colon cancers start?			
As a tear in the colon	1.8	1.1	1.4
As a polyp in the colon*	**93**	**96.8**	**94.7**
As a result of constipation	0	1.1	0.5
As a hemorrhoid	0.9	0	0.5
Missing	4.4	1.1	2.9
4. For each of the following mark whether or not it can increase the chance of a person getting colon cancer.			
a. Being over age 50			
Yes*	**85.1**	**82.8**	**84.1**
No	10.5	9.7	10.1
Missing	4.4	7.5	5.8

b. Having a history of inflammatory bowel disease			
Yes*	**67.5**	**54.8**	**61.8**
No	25.4	34.4	29.5
Missing	7.0	10.8	8.7
c. Having heart disease			
Yes	2.6	1.1	1.9
No*	**89.5**	**84.9**	**87.4**
Missing	7.9	14.0	10.6
d. Having a family history of colon cancer			
Yes*	**93.0**	**90.3**	**91.8**
No	3.5	4.3	3.9
Missing	3.5	5.4	4.3

5. You may not know exact number, but please take you best guess. Out of every 100 people, about how many will get colon cancer some time in their lives?			
Correct	**32.5**	**64.5**	**46.9**
Incorrect	67.5	35.5	53.1

6. Before some tests for colon cancer, people may be required to clean out their colon by drinking a lot of liquid that makes them move their bowels a lot. For each of the following colon cancer tests, mark whether or not it usually requires people to clean out their colon before the test.			
a. Stool Blood Test			
Yes	9.6	9.7	9.7
No*	**85.1**	**81.7**	**83.6**
Missing	5.3	8.6	6.8
b. Colonoscopy			
Yes*	**94.7**	**95.7**	**95.2**
No	2.6	3.2	2.9
Missing	2.6	1.1	1.9
c. Sigmoidoscopy			
Yes*	**58.8**	**79.6**	**68.1**
No	29.8	14.0	22.7
Missing	11.4	6.5	9.2
d. CT Scan			
Yes*	**28.1**	**60.2**	**42.5**
No	62.3	30.1	47.8

Missing	9.6	9.7	9.7
7. For each of the following colon cancer tests, mark whether or not it usually requires people to take medicine that makes them sleepy during the test			
a. Stool Blood Test			
Yes	2.6	2.2	2.4
No*	**90.4**	**86.0**	**88.4**
Missing	7.0	11.8	9.2
b. Colonoscopy			
Yes*	**88.6**	**96.8**	**92.3**
No	7.0	1.1	4.3
Missing	4.4	2.2	3.4
c. Sigmoidoscopy			
Yes	43.9	23.7	34.8
No*	**45.6**	**68.8**	**56.0**
Missing	10.5	7.5	9.2
d. CT Scan			
Yes	5.3	5.4	5.3
No*	**85.1**	**81.7**	**83.6**
Missing	9.6	12.9	11.1
8. For each of the following colon cancer tests, if there is abnormal test result, mark whether or not a follow up colonoscopy is needed			
a. Stool Blood Test			
Yes*	**82.5**	**80.6**	**81.6**
No	12.3	6.5	9.7
Missing	5.3	12.9	8.7
b. Colonoscopy			
Yes	57.9	40.9	50.2
No*	**33.3**	**48.4**	**40.1**
Missing	8.8	10.8	9.7
c. Sigmoidoscopy			
Yes*	**67.5**	**80.6**	**73.4**
No	21.1	8.6	15.5
Missing	11.4	10 (10.8	11.1
d. CT Scan			
Yes*	**64.9**	**82.8**	**72.9**
No	26.3	8.6	18.4
Missing	8.8	8.6	8.7
9. Does having a colon cancer test result that is not normal always mean that a person has colon cancer?			
Yes	2.6	5.4	3.9
No*	**93.0**	**94.6**	**93.7**
Missing	4.4	0	2.4

10. How often do serious problems, such as serious bleeding or tear in the colon, happen as a result of colonoscopy?			
Usually	0	3.2	1.4
Sometimes	22.8	10.8	17.4
Rarely*	**71.1**	**81.7**	**75.8**
Never	1.8	3.2	2.4
Missing	4.4	1.1	2.9
11. For a person with an average risk for colon cancer, which test do doctors recommend be done **every year**?			
Stool Blood Test*	**60.5**	**76.3**	**67.6**
Colonoscopy	24.6	15.1	20.3
Sigmoidoscopy	0.9	2.2	1.4
CT Scan	1.8	2.2	1.9
Selected more than one	5.3	0	2.9
Missing	7.0	4.3	5.8
12. For a person with an average risk for colon cancer, which test do doctors recommend be done every 10 years?			
Stool Blood Test	3.5	2.2	2.9
Colonoscopy*	**78.9**	**92.5**	**85.0**
Sigmoidoscopy	4.4	1.1	2.9
CT Scan	3.5	2.2	2.9
Selected more than one	5.3	1.1	3.4
Missing	4.4	1.1	2.9
13. How does regular testing for colon cancer change the chances that a person will die from colon cancer?			
Increases	2.6	2.2	2.4
Decreases*	**86.8**	**84.9**	**86.0**
Does not change	8.8	11.8	10.1
14. Which colon cancer test is least likely to miss a cancer?			
Stool Blood Test	30.7	15.1	23.7
Colonoscopy*	**41.2**	**61.3**	**50.2**
Sigmoidoscopy	3.5	3.2	3.4
CT Scan	13.2	12.9	13.0
Selected more than one	0.9	2.2	1.4
Missing	10.5	5.4	8.2
15. If the results of a colon cancer are normal, is it possible that a person could still have colon cancer?			
Yes*	**74.6**	**64.5**	**70.0**
No	18.4	31.2	24.2
Missing	7.0	4.3	5.8
16. You may not know exact number, but please take your best guess. Out of every 100 people, about how many will die of colon cancer?			
Correct	**41.2**	**73.1**	**55.6**
Incorrect	58.8	26.9	44.4

Note: Bolded items represent correct answer

Table 1. Comparing Colon Cancer Screening Choices

Screening option	Description	Preparation	Things to consider	Recommended schedule
Fecal Occult Blood Test (FOBT)	Collect stool samples at home to send to a lab. The samples are tested for traces of blood	No bowel preparation needed. Takes a few minutes to collect each sample	Can be done at home.	Once a year
Flexible Sigmoidoscopy (FSIG)	A flexible tube is used to look at the inside of the rectum and lower part of the colon to see if there are any polyps or abnormal growths	Before the test, the bowel must be cleaned out with an enema or a strong laxative. Test takes about 15-30 minutes	Is done in a doctor's office or hospital, usually without sedation. You may feel some pain or discomfort, but can leave on your own and drive home or return to work immediately.	Once every 5 years
FOBT + FSIG	FOBT 3 years combined with a FISG every 5 years	See above for preparation and time required.	Together, the two tests may be more effective than either test alone.	FOBT: every 3 years FSIG: every 5 years
Colonoscopy (CSPY)	A flexible tube is used to look at the inside of the rectum and the entire colon	Before the test, the bowel must be cleaned out with a strong laxative. Test takes 30-60 minutes. Afterwards, you'll need time at home to recover from the sedation.	Done in a doctor's office or hospital, usually with sedation. Usually not uncomfortable. You'll need someone to drive you home and you won't be able to return to work that day. If any polyps or abnormal growths are found, they can be removed for further testing	Once every 10 years
CT Colonoscopy (CTC or also called Virtual Colonoscopy)	A tube is used to introduce air into the colon, and a CT scan (or CAT scan) is used to take a picture of the colon from outside the body	Before the test, the bowel must be cleaned out with a strong laxative. Test takes 10-15 minutes. Recovery time is relatively short.	Done in a medical setting, often in a specialized CT room. Sedative not used. There may be some discomforts. Test still being studies to determine effectiveness.	Once every 5 years

**Except for CSPY, if any of these polyps are positive, CSPY should be performed*

Table 2. International Patient Decision Aid Standards Instrument and Ite

Dimension	Item
Information Providing information about options in sufficient detail for making a specific decision	1. The decision support technology describes the health cond problem (intervention, procedure or investigation) for which index decision is required
	2. The decision support technology describes the decision tha to be considered (the index decision)
	3. The decision support technology describes the options ava for the index decision
	4. The decision support technology describes the natural cou health condition or problem, if no action is taken.
	5. The decision support technology describes the positive fea (benefits or advantages) of each option
	6. The decision aid describes negative features (harms, side e disadvantages) of each option.
	7. The decision support technology makes it possible to comp positive and negative features of the available options.
	8. The decision support technology shows the negative and p features of options with equal detail (for example using simil order, and display of statistical information).
Probabilities Presenting outcome probabilities	1. The decision support technology provides information abo outcome probabilities associated with the options (i.e. the lik consequences of decisions)
	2. The decision support technology specifies the defined grou (reference class) of patients for which the outcome probabilit apply.
	3. The decision support technology specifies the event rates f outcome probabilities (in natural frequencies).
	4. The decision support technology specifies the time period which the outcome probabilities apply.
	5. The decision support technology allows the user to compa outcome probabilities across options using the same denomin time period.
	6. The decision support technology provides information abo levels of uncertainty around event or outcome probabilities (giving a range or by using phrases such as “our best estimate
	7. The decision support technology provides more than one v viewing the probabilities (e.g. words, numbers, and diagrams
	8. The decision support technology provides balanced inform about event or outcome probabilities to limit framing biases.
Values Clarifying and expressing	1. The decision support technology describes the features of to help patients imagine what it is like to experience the phys effects.
	2. The decision support technology describes the features of

values	to help patients imagine what it is like to experience the psychological effects.
	3. The decision support technology describes the features of options to help patients imagine what it is like to experience the social effects.
	4. The decision support technology asks patients to think about which positive and negative features of the options matter most to them.
Decision Guidance Structured guidance in deliberation & communication	1. The decision support technology provides a step-by-step way to make a decision.
	2. The decision support technology includes tools like worksheets or lists of questions to use when discussing options with a practitioner.
Development Using a systematic development process	1. The development process included finding out what clients or patients need to prepare them to discuss a specific decision
	2. The development process included finding out what health professionals need to prepare them to discuss a specific decision with patients
	3. The development process included expert review by clients/patients not involved in producing the decision support technology
	4. The development process included expert review by health professionals not involved in producing the decision aid.
	5. The decision support technology was field tested with patients who were facing the decision.
	6. The decision support technology was field tested with practitioners who counsel patients who face the decision.
Evidence Using evidence	1. The decision support technology (or associated documentation) provides citations to the studies selected.
	2. The decision support technology (or associated documentation) describes how research evidence was selected or synthesized.
	3. The decision support technology (or associated documentation) provides a production or publication date.
	4. The decision support technology (or associated documentation) provides information about the proposed update policy.
Disclosure Disclosure and transparency	1. The decision support technology (or associated technical documentation) provides information about the funding used for development.
	2. The decision support technology includes author/developer credentials or qualifications.
Plain Language Using plain language	1. The decision support technology (or associated documentation) reports readability levels (using one or more of the available scales).

DST Evaluation	1. There is evidence that the decision support technology improves the match between the features that matter most to the informed patient and the option that is chosen
	2. There is evidence that the patient decision support technology helps patients improve their knowledge about options' features
Test (for DSTs that are directed at investigations or screening tests)	1. The decision support technology describes what the test is designed to measure.
	2. The decision support technology includes information about the chances of having a true positive test result.
	3. The decision support technology includes information about the chances of having a true negative test result.
	4. The decision support technology includes information about the chances of having a false positive test result.
	5. The decision support technology includes information about the chances of having a false negative test result.
	6. If the test detects the condition or problem, the decision support technology describes the next steps typically taken.
	7. The decision support technology describes the next steps if the condition or problem is not detected.
	8. The decision support technology describes the chances that the disease is detected with and without the use of the test.
	9. The decision support technology has information about the consequences of detecting the condition or disease that would never have caused problems if screening had not been done (lead time bias).

***** *The instrument represents the work of the International Patient Decision Aid Standards Collaboration developed to measure the quality of patient decision support technologies (decision aids)* **[78].**

Table 3. Primary and Secondary Outcomes Used to Measure Effectiveness of Decision Aids on Colon Cancer Screening in Randomized Controlled Trials

Investigator (Year)	Decision aid (screening options included)	Measures of outcomes	
		Primary outcome(s)	Secondary outcome(s)
Meade (1994)[12]	No description of screening choices	Knowledge about colon cancer	None
Pignone (2000)[8]	FOBT, FSIG or either	Treatment undergone	Intent to undergo screening
Wolf (2000)[10]	FOBT, FSIG or both	Intent to begin or continue screening, realistic expectation	Patients' estimate of FOBT positive predictive value and patients' perception of CRC mortality reduction by screening
Dolan (2002)[5]	FOBT, FSIG, both FOBT and FSIG, DCBE and CSPY	Knowledge and decision process	Decision outcomes
Ruffin (2007)[135]	FOBT, FSIG, DCBE and CSPY	CRC screening completion (yes/no)	Preferred method for CRC screening

Table 4. Participant and Respondent Characteristics, by Treatment Group

Patient Characteristic Total n = 207	Participants (n = 271) Control (n = 136)	Participants (n = 271) Intervention (n = 135)	Respondents (n = 207) Control (n = 114)	Respondents (n = 207) Intervention (n = 93)
Age, *mean* (s.d.)	60 (±7.5)	59 (±7.9)	60 (±7.1)	60 (±8.2)
Female, %	58	59	60	63
Race, % Black	52	52	47	53
Non-Black	49	48	53	47
BMI, *mean* (s.d.)	31 (±9.1)	30 (±7.7)	31 (± 9.6)	30 (±8.1)
College graduate, %				
Yes	47	53	52	52
No	51	47	47	47
Missing	2	1	2	1
Married or living as married, %				
Yes	40	41	37	43
No	52	56	54	56
Missing	7	3	9	1
Currently employed, %				
Yes	**55**	**75**	**54**	**72**
No	**44**	**25**	**45**	**28**
Missing	**1**	**0**	**1**	**0**
Income, % < $75,000	**43**	**55**	**43**	**55**
≥ $75,000	**32**	**36**	**34**	**38**
Missing	**25**	**9**	**23**	**8**
Self-rated health, % Excellent	16	14	18	15
Very good	28	35	27	41
Good	32	36	33	29
Fair	18	9	16	11
Poor	2	1	2	0
Missing	4	5	4	4
Response rate, %	**84**	**69**		
Knowledge score, *mean* (s.d.)			**72 (±15)**	**80 (±18)**
Prior experience with CSPY, %				
Yes			35	30
No			62	66
Missing			3	4
Physician recommendation for CSPY, % Yes			91	89
No			6	8
Missing			3	3

**Bolded items show difference between two groups statistically significant at p <0.05 levels in univariate analyses*

Note: percentages may add up to more than 100% due to rounding

Table 5. Distribution of Responses for CRC Screening Decision

Survey Questions	Responses (%)	n = 207
For each of the following colon cancer tests, please mark whether or not any doctor or health professional ever talked to you about it	FOBT FSIG CSPY CTC	47 22 86 10
For each of the following colon cancer tests, please mark whether or not any doctor or health professional ever recommended it to you	FOBT FSIG CSPY CTC	37 13 90 4
Did your doctors explain that there were choices in what you could do for colon cancer screening?	Yes	45
How much did your health care providers talk about the reasons to be tested for colon cancer	A lot Some A little Not at all	24 45 22 8
How much did your health care provider talk about the reasons NOT to be tested for colon cancer?	A lot Some A little Not at all	6 11 13 66
Did any of your health care provider ask which type of colon cancer test you wanted?	Yes	19

Note: percentages may not add up to 100% due to missing data

Table 6. Distribution of Responses to Select Questions on the Knowledge Test in DQI

Survey item	% Correct		
	Control	Intervention	*p* - value
5. You may not know exact number but please take your best guess. Out of every 100 people, about how many will get colon cancer some time in their lives?			
Correct	32.5	64.5	<0.0001
Incorrect	67.5	35.5	
7. For each of the following colon cancer tests mark whether or not it usually requires people to take medicine that makes them sleepy during test			
Colonoscopy			
Yes*	88.6	96.8	0.03
Sigmoidoscopy			
No*	45.6	68.8	0.0008
8. For each of the following colon cancer tests, if there is abnormal test result, mark whether or not a follow up colonoscopy is needed			
Colonoscopy			
No*	33.3	48.4	0.03
Sigmoidoscopy			
Yes*	67.5	80.6	0.03
CT Scan			
Yes*	64.9	82.8	0.004
16. You may not know exact number, but please take your best guess. Out of every 100 people, about how many will die of colon cancer?			
Correct	41.2	73.1	<0.0001
Incorrect	58.8	26.9	

**Represents correct answer*

Table 7. Respondent Characteristics Associated with Knowledge in ITT Univariate and PP Multivariate Analyses

Respondent Characteristics (n = 207)		Univariate (n = 207)		ITT Multivariate (n = 207)		PP Multivariate (n = 196)	
		Mean knowledge, % correct	*p*-value	Regression coefficient	*p*-value	Regression coefficient	*p*-value
Study Group	Intervention	80.4 (±17.8)	0.0006	8.3	< 0.0001	8.9	< 0.0001
	Control	72.3 (±15.4)					
Age group	50-59	76.8 (±15.9)	0.40				
	60-69	76.4 (±18.6)					
	70-80	72.1 (±16.8)					
Gender	Male	74.8 (±16.6)	0.22				
	Female	77.8 (±17.2)					
Race	Black	69.3 (±18.3)	< 0.0001	-8.6	0.005	-9.0	0.0003
	Non-black	82.1 (±13.0)					
College graduate	Yes	81.9 (±14.4)	< 0.0001	5.4	0.04	5.5	0.04
	No	69.6 (±17.4)					
Prior screening hx	Yes	76.0 (±16.6)	0.94				
	No	75.8 (±17.5)					
Income	< $75,000	72.0 (±17.2)	< 0.0001	-5.6	0.03	-5.1	0.06
	≥ $75,000	84.0 (±12.3)					
	Missing	70.0 (±19.5)	< 0.0001	-8.2	0.01	-7.2	0.03
Employed	Yes	76.8 (±16.1)	0.33				
	No	74.4 (±18.3)					

Note: multivariate analysis controlled for the intervention, race, college education and income

Table 8. Table 8. Respondents' Self-Report of Test Preference

Preferred screening test (%)	Control (n = 114)	Intervention (n = 93)
CSPY	61	70
FOBT	14	10
CT Colonography	7	6
No screening	7	6
Combination of FOBT and FSIG	4	5
FSIG	3	1
Undecided	3	0

Note: percentages may not add up to 100% due to missing data

Table 9. Respondent Characteristics, by Screening Preference for CSPY

Respondent Characteristics	ITT Univariate			ITT Multivariate
	Does Not Prefer CSPY (n = 66)	Prefers CSPY (n = 135)	*p* - value	Odds ratio of choosing CSPY (95% CI)
Study group (intervention), %	39	48	0.20	
Age, mean (s.d.)	61 (±7.9)	59 (±7.7)	0.25	
Female, %	**71**	**56**	**0.04**	**0.46 (0.24, 0.99)**
Race, %				
Black	49	50	0.89	
Non-black	51	50		
BMI, mean (s.d.)	31 (± 11)	31 (±8)	0.90	
College graduate, % Yes	53	51	0.82	
No	46	47		
Married or living as married, %	38	41	0.66	
Currently employed, % Yes	**53**	**67**	**0.03**	**2.0 (1.0, 3.8)**
No	**47**	**32**		
Income				
< $75,000	51	47	0.51	
≥ $75,000 and above	31	39		
Missing	18	15		
Knowledge score, *mean* (s.d.)	74 (±19)	77 (±16)	0.09	
Prior experience with CSPY, % Yes	**18**	**41**	**0.001**	**2.8 (1.3, 5.9)**
No	**78**	**56**		
Physician recommendation for CSPY, %				
Yes	**81**	**96**	**0.005**	**5.9 (1.7, 21.3)**
No	**14**	**3**		
Self-rated health, %				
Excellent	8	22	0.12	
Very good	35	33		
Good	35	29		
Fair	15	13		
Poor	0	2		
Missing	7	3		

Table 10. Results from Multivariate Logistic Regression Using Values to Predicting the Odds of Choosing CSPY

Value items	Odds Ratio (95% CI)
Finding colon cancer or polyps early	1.31 (1.12, 1.53)
To avoid a test that requires you to handle your stool	1.20 (1.08, 1.33)
To avoid a test where a tube is put into your rectum to look at the colon	0.77 (0.68, 0.86)

Table 11. Univariate and Multivariate Comparisons of Odds Ratios from Two Study Groups with Regard to Respondents' Preference for CSPY

	ITT (n = 207)			PP (n = 196)		
Factor	**Control (n = 114)**	**Intervention (n= 93)**	OR Study arm *value	**Control (n = 114)**	**Intervention (n = 82)**	OR Study arm*value
Find colon cancer or polyps early	**1.46 (1.16, 1.82)**	1.22 (0.99, 1.51)	0.84 (0.62,1.14)	**1.46 (1.16, 1.82)**	**1.33 (1.05, 1.68)**	0.91 (0.66, 1.26)
Know whether or not you have colon cancer	**1.35 (1.10, 1.65)**	**1.21(1.01, 1.45)**	0.90 (0.68,1.19)	**1.35 (1.10, 1.65)**	**1.28 (1.05, 1.56)**	0.95 (0.71, 1.26)
Choose a test that does not need to be done every year	0.99 (0.87 1.12)	1.11 (0.96, 1.27)	1.12 (0.93, 1.35)	0.99 (0.87, 1.12)	1.11 (0.96, 1.29)	1.12 (0.92, 1.37)
Choose a test where you take sedative	1.05 (0.94, 1.17)	1.00 (0.89, 1.13)	0.96 (0.81, 1.12)	1.05 (0.94, 1.17)	0.99 (0.86, 1.34)	0.94 (0.79, 1.12)
Choose a test that doesn't cost a lot	0.98 (0.88, 1.09)	0.98 (0.86, 1.11)	1.00 (0.84, 1.18)	0.98 (0.88, 1.09)	0.97 (0.83, 1.12)	0.99 (0.82, 1.18)
Avoid handling stool	**1.17 (1.05, 1.31)**	1.04 (0.92, 1.16)	0.89 (0.76, 1.04)	**1.17 (1.05, 1.31)**	1.09 (0.95, 1.25)	0.94 (0.78, 1.12)
Avoid pain	1.02 (0.92, 1.16)	0.96 (0.81, 1.13)	0.94 (0.76, 1.15)	1.02 (0.90, 1.16)	0.99 (0.82, 1.19)	0.97 (0.78, 1.21)
Avoid a tube	**0.87 (0.78, 0.97)**	**0.74 (0.63, 0.87)**	0.85 (0.70, 1.04)	**0.87 (0.78, 0.97)**	**0.77 (0.64, 0.91)**	0.88 (0.72, 1.09)
Avoid bleeding or a tear in the colon	0.92 (0.78, 1.09)	**0.81 (0.67, 0.98)**	0.88 (0.68, 1.14)	0.92 (0.78, 1.09)	0.82 (0.66, 1.00)	0.89 (0.68, 1.16)
Avoid drinking a bowel prep	0.96 (0.86, 1.08)	**0.83 (0.71, 0.96)**	0.86(0.71, 1.03)	0.96 (0.86 1.08)	0.86 (0.74, 1.01)	0.90 (0.74, 1.09)

**Bolded items statistically significant at 0.05 level*

Table 12. Values Concordance Scores Associated with Choosing CSPY in T
Study Groups Based on Univariate Logistic Regression

Value concordance (% Match)	Control (n = 114)	ITT Intervention (n = 93)	PP Intervention (n = 82)
To try to find colon cancer or polyps early	71	68	74
To know whether or not you have colon cancer	70	68	72
To choose a test that does not need to be done every year	62	64	73
To choose a test where you take medicine before the test that makes you sleepy	63	69	73
To choose a test that doesn't cost you a lot of money	63	69	72
To avoid a test that requires you to handle your stool	62	70	73
To avoid a test that may be painful	62	69	73
To avoid a test where a tube is put into your rectum to look at the colon	67	70	75
To avoid a test that can cause bleeding or a tear in the colon	62	70	73
To avoid a test where you have to drink a liquid before the test to clean out the colon	63	71	74

Note: respondents who reported preference for CSPY who also had predicted mo probabilities ≥ 0.5 and who did not prefer CSPY who also had predicted model probabilities < 0.5 were considered to have value concordance

Table 13. Univariate and Multivariate Comparisons of Odds Ratios in Two Study Groups with Regard to Respondents' Preference for FOBT

	ITT (n = 207)			PP (n = 196)		
Factor	**Control (n = 114)**	**Intervention (n= 93)**	OR Study arm *value	**Control (n = 114)**	**Intervention (n = 82)**	OR Study arm*value
Find colon cancer or polyps early	0.85 (0.70, 1.02)	1.24 (0.73, 2.12)	1.5 (0.84, 2.59)	0.85 (0.70, 1.02)	1.24 (0.60, 2.55)	1.46 (0.69, 3.09)
Know whether or not you have colon cancer	0.87 (0.71, 1.06)	0.92 (0.73, 1.18)	1.07 (0.78, 1.46)	0.87 (0.71, 1.06)	0.88 (0.67, 1.15)	1.01 (0.72, 1.42)
Choose a test that does not need to be done every year	0.94 (0.79, 1.12)	0.92 (0.75, 1.12)	0.98 (0.75, 1.27)	0.94 (0.79, 1.12)	0.84 (0.66, 1.07)	0.89 (0.66, 1.20)
Choose a test where you take sedative	0.93 (0.80, 1.08)	1.02 (0.84, 1.24)	1.10 (0.86, 1.40)	0.93 (0.80, 1.08)	1.03 (0.80, 1.33)	1.11 (0.82, 1.49)
Choose a test that doesn't cost a lot	1.08 (0.91, 1.27)	1.24 (0.96, 1.59)	1.15 (0.85, 1.55)	1.08 (0.91, 1.27)	1.30 (0.90, 1.88)	1.21 (0.81, 1.81)
Avoid handling stool	**0.71 (0.56, 0.89)**	0.96 (0.80, 1.15)	**1.35 (1.01, 1.81)**	**0.71 (0.56, 0.89)**	0.91 (0.70, 1.19)	1.29 (0.92, 1.83)
Avoid pain	0.96 (0.81, 1.14)	0.96 (0.75, 1.23)	1.00 (0.74, 1.35)	0.96 (0.81, 1.14)	0.82 (0.60, 1.11)	0.85 (0.60, 1.21)
Avoid a tube	1.18 (0.99, 1.41)	**1.41 (1.08, 1.85)**	1.20 (0.87, 1.65)	1.18 (0.99, 1.41)	**1.48 (1.02, 2.16)**	1.26 (0.83, 1.90)
Avoid bleeding or a tear in the colon	1.09 (0.84, 1.41)	1.22 (0.88, 1.69)	1.12 (0.74, 1.70)	1.09 (0.84, 1.41)	1.25 (0.80, 1.94)	1.14 (0.69, 1.91)
Avoid drinking a bowel prep	0.98 (0.83, 1.15)	**1.35 (1.04, 1.75)**	**1.38 (1.02, 1.88)**	0.98 (0.83, 1.15)	1.15 (0.86, 1.53)	1.18 (0.85, 1.64)

**Bolded items statistically significant at 0.05 level*

Table 14. The Colorectal Cancer Decision Aid: Comparing test effectiven

Screening Option	Schedule	Effectiveness
Stool test for blood (FOBT)	Every year	Effective
Sigmoidoscopy	Every 5 years	Effective
CT colonography	Every 5 years	More effective
Colonoscopy	Every 10 years	Most effective
Stool tests for blood + sigmoidoscopy	Every 3 years; Every 5 years	Most effective

Note: this table appears on p.24 of the Colorectal Cancer Decision Aid. The tabl copied with permission from the Foundation for the Informed Medical Decision Making.

Figure 1. The Ottawa Decisional Framework

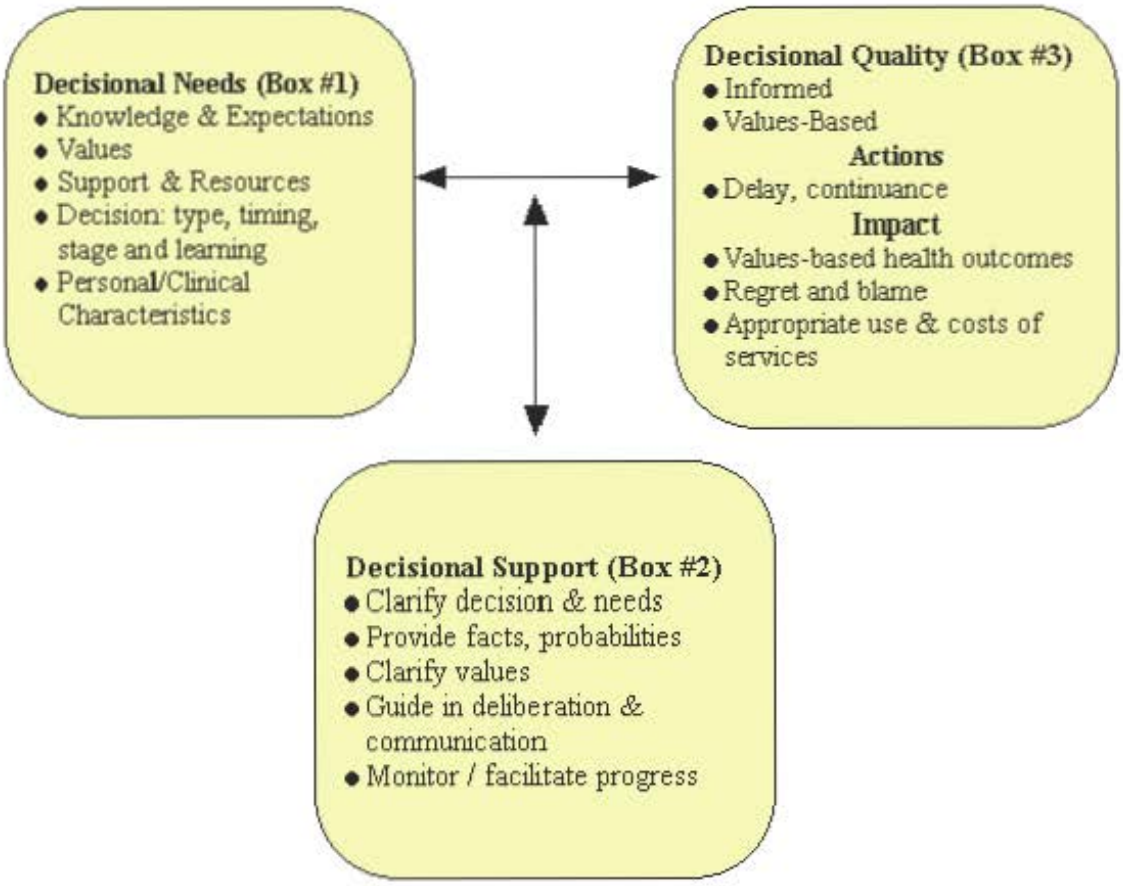


Figure 2. Study Recruitment Process

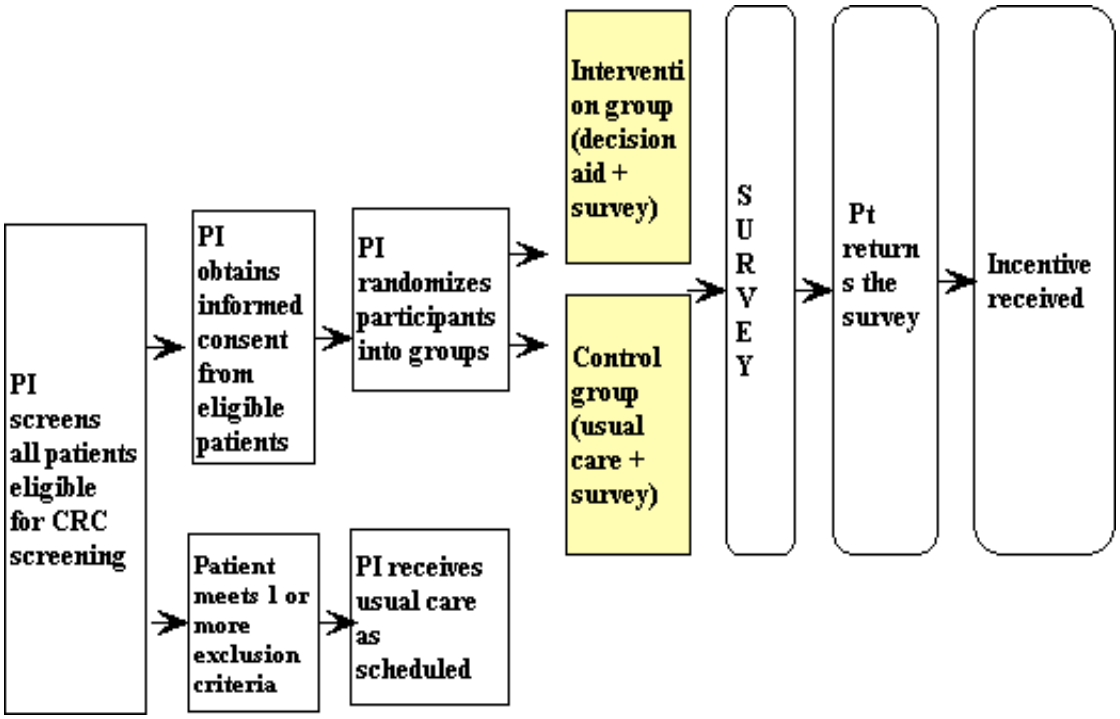
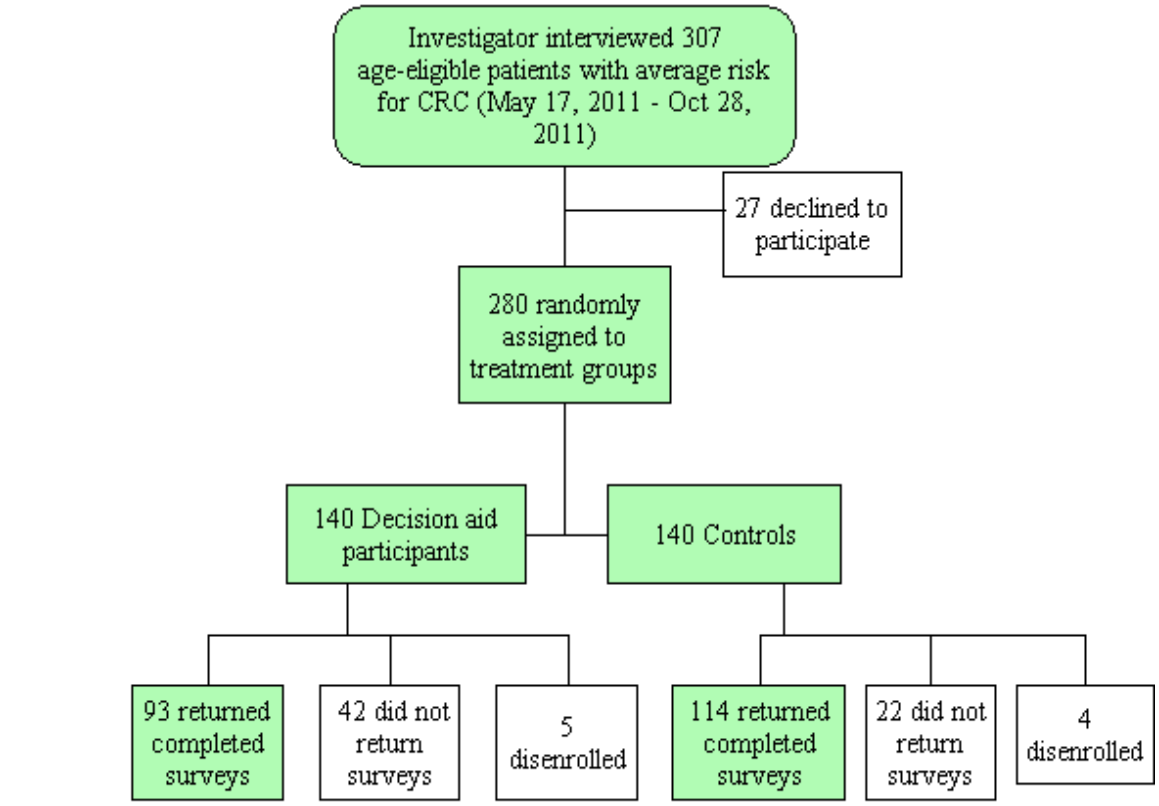
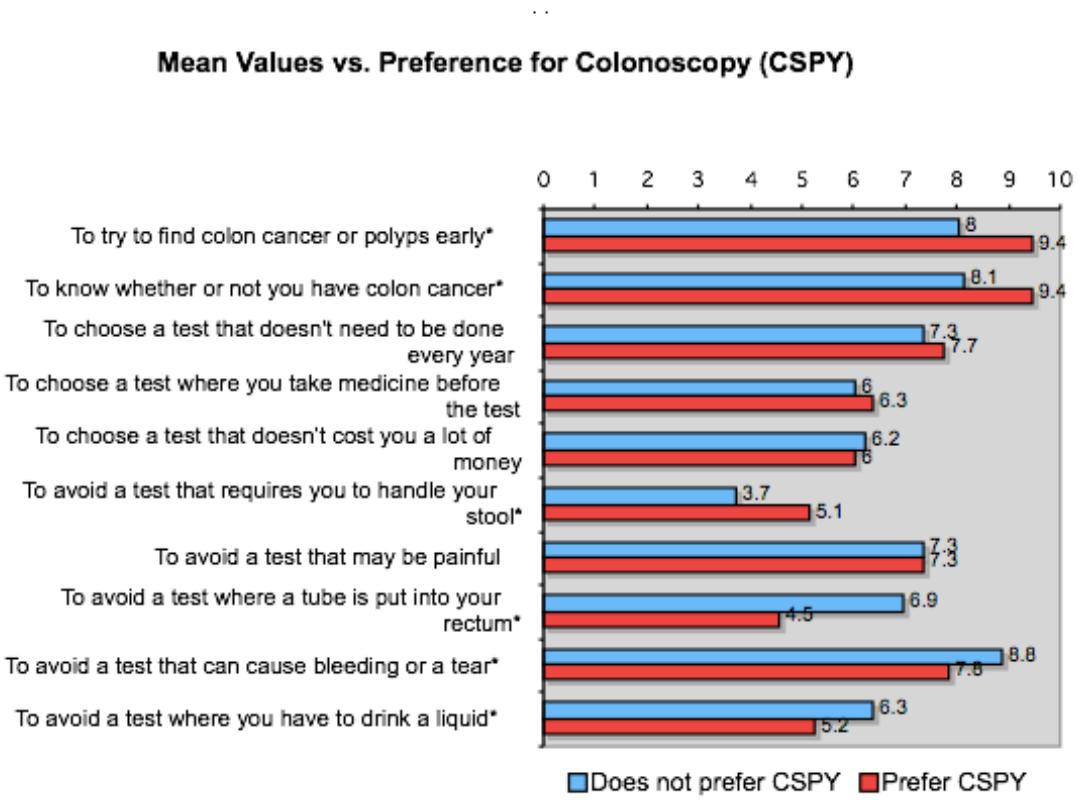


Figure 3. Study Flow Diagram



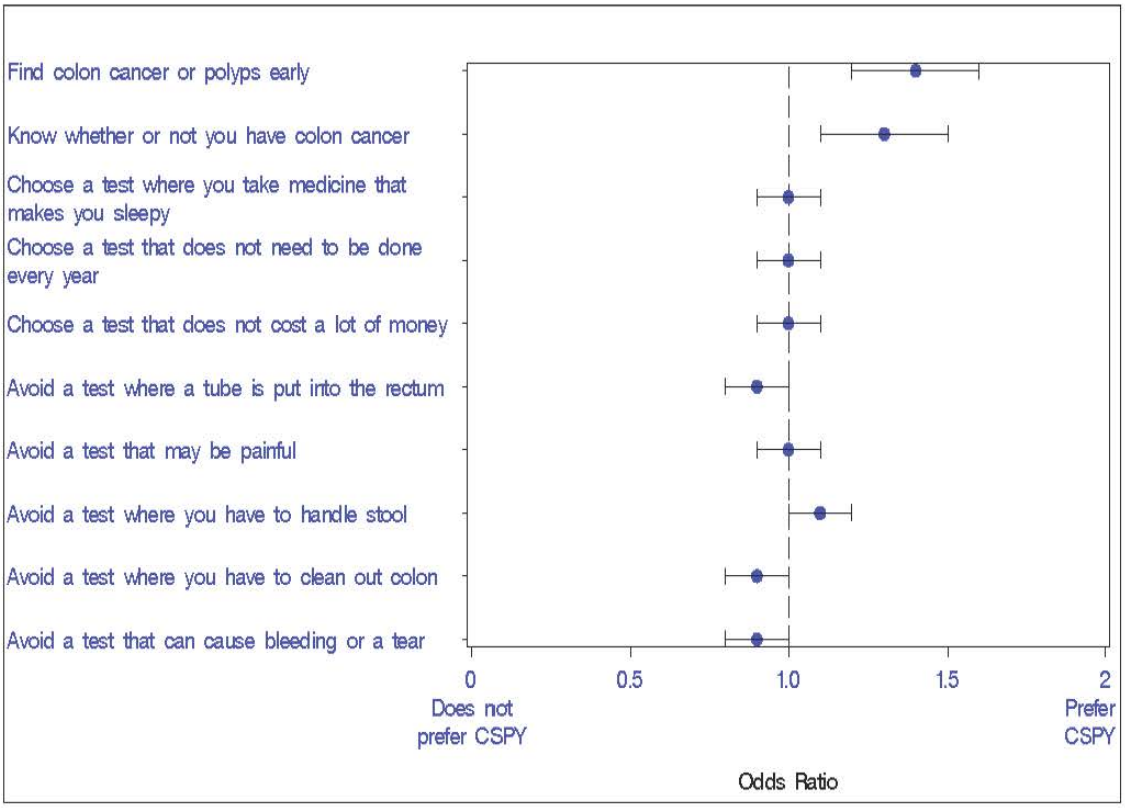
* PI = Principal investigator

Figure 4. ITT Comparison of Mean Value Scores between Respondents with Preference for and against CSPY



** Mean value scores (*p < 0.05 on univariate logistic regression)*

Figure 5. Patient Values Predicting Choice in ITT Univariate Analysis



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